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UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

SOUTHEAST ALASKA REGIONAL
HEALTH CONSORTIUM,

Plaintiff,

vs.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY; RHODES
PHARMACEUTICALS, L.P.; RHODES
TECHNOLOGIES, INC.; CEPHALON,
INC.; TEVA PHARMACEUTICAL
INDUSTRIES, LTD.; TEVA
PHARMACEUTICALS USA, INC;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC.
N/K/A JANSSEN PHARMACEUTICALS,
INC.; NORAMCO, INC.; ENDO HEALTH
SOLUTIONS INC.; ENDO

Case No.: 3:18-cv-00217-TMB
COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

1 PHARMACEUTICALS INC.; ENDO
2 INTERNATIONAL PLC; PAR
3 PHARMACEUTICAL, INC.; PAR
4 PHARMACEUTICALS COMPANIES,
5 INC. F/K/A PAR PHARMACEUTICAL
6 HOLDINGS, INC.; ALLERGAN PLC
7 F/K/A ACTAVIS PLC; ALLERGAN
8 FINANCE LLC, F/K/A ACTAVIS, INC.,
9 F/K/A WATSON PHARMACEUTICALS,
10 INC.; WATSON LABORATORIES, INC.;
11 ACTAVIS LLC; ACTAVIS PHARMA,
12 INC. F/K/A WATSON PHARMA, INC.;
13 INSYS THERAPEUTICS, INC.;
14 MALLINCKRODT PLC;
15 MALLINCKRODT, LLC; SPECGX LLC;
16 ABBOTT LABORATORIES; ABBOTT
17 LABORATORIES, INC; AMNEAL
18 PHARMACEUTICALS, INC F/K/A
19 AMNEAL PHARMACEUTICALS, LLC;
20 KVK-TECH, INC.; MCKESSON CORP.;
21 CARDINAL HEALTH, INC.; CARDINAL
22 HEALTH 110, LLC;
23 AMERISOURCEBERGEN CORP.; ANDA,
24 INC.; ANDA PHARMACEUTICALS,
25 INC.; HENRY SCHEIN, INC.; HENRY
26 SCHEIN MEDICAL SYSTEMS, INC.; and
27 JOHN & JANE DOES 1-100 INCLUSIVE,
Defendants.

COMPLAINT

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1 I. INTRODUCTION

2
3 1. An epidemic of opioid abuse is devastating the United States. Opioid
4 analgesics are widely diverted and improperly used, and the widespread abuse of opioids has
5 resulted in a national epidemic of opioid overdose deaths and addictions.¹ The opioid epidemic
6 is “directly related to the increasingly widespread misuse of powerful opioid pain
7 medications.”²

8
9 2. The cause of this epidemic and the conditions for its acceleration were
10 intentionally brought about by Defendants, who manufacture and distribute prescription
11 opioids and who have made billions of dollars off the epidemic. The Defendants’ unlawful
12 marketing, sales, and distribution of prescription opioids resulted in the diversion, misuse,
13 overdose and addiction described below.

14
15 3. Opioids are now the leading cause of accidental death in the U.S.,
16 surpassing deaths caused by car accidents. Opioid overdose deaths (which include prescription
17 opioids as well as heroin) have risen steadily every year, from approximately 4,030 in 1999, to
18 15,597 in 2009, and to over 33,000 in 2015. In 2016, that toll climbed to 53,000.³ The recent
19 surge in opioid-related deaths involves prescription opioids, heroin, and other synthetic
20 opioids.
21

22 ¹ See Nora D. Volkow & A. Thomas McLellan, *Opioid Abuse in Chronic Pain - Misconceptions and Mitigation*
23 *Strategies*, 374 N. Engl. J. Med. 1253 (2016), <https://www.nejm.org/doi/full/10.1056/nejmra1507771> (last accessed
24 August 6, 2018).

25 ² See Robert M. Califf et al., *A Proactive Response to Prescription Opioid Abuse*, 374 N. Engl. J. Med. 1480 (2016),
26 <https://www.nejm.org/doi/full/10.1056/NEJMSr1601307> (last accessed August 6, 2018).

27 ³ *Overdose Death Rates*, NIH National Institute on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Aug. 2018).

1 4. More than half of all drug overdose deaths involve an opioid drug like those
2 manufactured by Defendants,⁴ and the increase in overdoses from non-prescription opioids is
3 directly attributable to Defendants' success in expanding the market for opioids of any kind. In
4 2016, the number of overdose deaths involving opioids (including prescription opioids and
5 illegal opioids like heroin and illicitly manufactured fentanyl) was 5 times higher than in 1999.⁵
6

7 5. Communities throughout the State of Alaska have been devastated by the
8 opioid epidemic brought about by Defendants' conduct. On February 14, 2017, the Governor
9 of the State of Alaska issued a Declaration of Disaster Emergency "in response to the growing
10 number of overdoses attributed to opioid use," declaring that "an outbreak and a condition of
11 public health disaster emergency exists statewide[.]"⁶
12

13 6. In 2012, Alaska's prescription opioid pain reliever overdose death rate was
14 more than double the rate in the U.S. (10.5 vs. 5.1 per 100,000 persons, respectively), and
15 Alaska's heroin-associated overdose death rate was over 50% higher than the national rate (3.0
16 vs. 1.9 per 100,000 persons, respectively).⁷
17

18 7. In 2013, Alaska's drug overdose death rate (14.4 per 100,000 persons)
19 exceeded the national rate (13.8 per 100,000 persons).
20

21 8. Further, "the impact of the opioid crisis on American Indians and Alaska
22 Natives is immense. The Centers for Disease Control and Prevention (CDC) reported that
23

24 ⁴ *Understanding the Epidemic*, Centers for Disease Control and Prevention,
<https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017) (last accessed August 6,
2018).

25 ⁵ *Id.*

26 ⁶ Governor Bill Walker, State of Alaska Declaration of Disaster Emergency, https://gov.alaska.gov/wp-content/uploads/sites/5/2017021417_Opioid-Disaster-Declaration.pdf.

27 ⁷ State of Alaska Epidemiology Bulletin, DHHS, *Drug Overdose Deaths in Alaska, 2009-2015*, No. 6, March 24, 2016, http://www.epi.alaska.gov/bulletins/docs/b2016_06.pdf

1 American Indians and Alaska Natives had the highest drug overdose death rates in 2015 and
2 the largest percentage increase in the number of deaths over time from 1999-2015 compared to
3 other racial and ethnic groups. During that time, deaths rose more than 500 percent among
4 American Indians and Alaska Natives.”⁸

5
6 9. Health care providers throughout the State of Alaska, including Alaska
7 Native tribal health organizations, have faced overwhelming costs as a direct result of this
8 public health crisis. Plaintiff SouthEast Alaska Regional Health Consortium (SEARHC), which
9 provides health care services to Alaska Natives, American Indians, and other eligible
10 individuals in the State of Alaska, has suffered substantial loss of resources, economic
11 damages, and increased costs in responding to the opioid epidemic.

12
13 10. The effects of the opioid crisis have been exacerbated by Defendants’ efforts
14 to conceal or minimize the risks of—and to circumvent or ignore safeguards against—opioid
15 abuse. Instead of acting with reasonable care and in compliance with their legal duties, the
16 Defendants intentionally flooded the market with opioids and pocketed billions of dollars in the
17 process.

18
19 11. Defendants pursued a knowing, deliberate and deceptive campaign to
20 persuade both doctors and patients that prescription opioids could and should be used long-
21 term to treat chronic pain, and that they posed a low risk of addiction. Those claims were false

22
23 ⁸ Cynthia Gunderson, *The IHS Launches New Opioids Website*, Indian Health Service,
24 <https://www.ihs.gov/newsroom/ihs-blog/july2018/the-ihs-launches-new-opioids-website/>; *Illicit Drug Use, Illicit*
25 *Drug Use Disorders, and Drug Overdose Deaths in Metropolitan and Nonmetropolitan Areas – United States*, 66
26 *Morbidity and Mortality Wkly. Rep.* 1, CDC (Oct. 20, 2017),
27 <https://www.cdc.gov/mmwr/volumes/66/ss/pdfs/ss6619.pdf>

1 and unsupported by scientific evidence⁹, and Defendants were aware of that at the time they
2 were made. Nevertheless, through ongoing, fraudulent marketing, the Defendants transformed
3 medical thinking about opioids. Defendants convinced doctors that the risk of addiction was
4 modest and manageable, and outweighed by the benefits in reduced pain and improved quality
5 of life for their patients; that it was safe to prescribe opioids previously used only for acute pain
6 for long-term use; and that abuse-deterrent technology was effective in curbing opioid misuse
7 and abuse.
8

9 12. Moreover, the prescription drug industry is required by statute and regulation
10 to secure and monitor opioids at every step of the stream of commerce, thereby protecting
11 opioids from theft, misuse, and diversion. The industry is also supposed to implement
12 processes to alert it to “red flags” that stop suspicious or unusual orders by pharmacies, doctors,
13 clinics, or patients. Defendants utterly failed to meet these obligations with respect to the
14 opioid drugs they sold and distributed, despite their ability to do so.
15

16 13. Defendants, through their actions, thus fueled the opioid epidemic for their
17 own financial gain, causing the United States as a whole, the State of Alaska, and the
18 geographic region within the State served by the Plaintiff, in particular, to be flooded with
19 opioids. Defendants created an environment where opioid diversion and abuse is rampant.
20 Such diversion and abuse was an entirely foreseeable result of the Defendants’ actions in
21 intentionally creating an inflated market for dangerously addictive drugs through, in part,
22 concealing the risks of addiction, and in shipping massive quantities of such drugs throughout
23
24

25 ⁹ See Letter from Vivek H. Murthy, U.S. Surgeon General, August 2016, available at <http://turnthetidex.org/> (last
26 accessed August 10, 2018).
27

1 the United States without taking reasonable and necessary steps to prevent diversion and
2 misuse.

3 14. Defendants' actions directly and foreseeably caused damages to the
4 Plaintiff, including but not limited to the costs of (a) providing medical and therapeutic care,
5 and prescription drug purchases (including prescribing and administering opioids based on
6 Defendants' widespread and pervasive campaign of misinformation); (b) treatment costs for
7 patients suffering from opioid addiction or disease, overdose, or death, including unreimbursed
8 costs; (c) counseling, treatment and rehabilitation services; (d) treatment of infants born with
9 opioid-related medical conditions; (e) lost opportunity costs; (f) increased human resource costs;
10 (g) the diversion of funding from other needed health care programs and services and (h) lost
11 opportunity costs. These damages have been suffered and continue to be suffered directly by
12 the Plaintiff, who are specifically responsible for the provision of health care and related
13 services to eligible populations at no cost or reduced cost, among other things.
14

15
16 15. The Plaintiff seeks injunctive relief, compensatory and statutory damages, as
17 well as the means to abate the epidemic created by Defendants' wrongful and/or unlawful
18 conduct.
19

20 II. THE PARTIES

21 A. The Plaintiff

22 16. Plaintiff is a Tribal Health Organization in Alaska providing health care
23 services to American Indians and Alaska Natives, and to other eligible individuals in the State
24 of Alaska, pursuant to Title V of the Indian Self-Determination and Education Assistance Act
25 (ISDEAA), 25 U.S.C. §§ 5301, *et seq.*, and the Alaska Tribal Health Compact. The ISDEAA
26
27

1 authorizes tribes and tribal organizations like the Plaintiff to enter into contracts and compacts
2 to assume responsibility to provide programs and services that the federal government would
3 otherwise be obligated to provide for the benefit of American Indians and Alaska Natives. The
4 Alaska Tribal Health Compact is the umbrella agreement, entered into between Alaska Native
5 Tribes and tribal organizations in Alaska and the Indian Health Service (IHS) pursuant to Title
6 V of the ISDEAA, that authorizes those tribes and tribal organizations to operate health and
7 health-related programs formerly operated by the IHS. In addition, each tribal co-signer to the
8 Alaska Tribal Health Compact enters into separate funding agreements with the IHS that
9 govern the scope of programs and services to be performed.
10

11
12 17. Over 99% of the IHS budget in Alaska is administered by tribes and tribal
13 health programs under the Alaska Tribal Health Compact and other ISDEAA agreements. The
14 Alaska Tribal Health System, which administers these programs and services, is composed of
15 individual tribes and Tribal Health Organizations throughout the State, twelve regional health
16 consortia, and a statewide consortium, all of which are interconnected through sophisticated
17 patterns of referral.
18

19 18. Plaintiff is a non-profit health consortium, and one of the Alaska Tribal
20 Health System's twelve regional Tribal Health Organizations, serving the health needs of the
21 residents of Southeast Alaska with its principal place of business in Juneau, Alaska. Plaintiff,
22 itself a consortium of fifteen Alaska Native tribes in Southeast Alaska, was established in 1975
23 under the provisions of the ISDEAA. Plaintiff is one of the oldest and largest Native-run health
24 organizations in the nation.
25
26
27

1 19. Plaintiff currently provides health care and health related services in 28
2 communities throughout Southeast Alaska. Additionally, Plaintiff operates 16 primary care
3 clinics and provides seasonal primary care services in the most remote locations in Southeast
4 Alaska. Plaintiff also operates the Mt. Edgecumbe Hospital in Sitka, a critical access regional
5 facility that is open to everyone in Sitka and Southeast Alaska, and the Ethel Lund Medical
6 Center in Juneau. Further, in accordance with the Emergency Medical Treatment and Active
7 Labor Act (EMTALA), Plaintiff provides emergency medical screening and stabilization to all
8 individuals, including those who are not otherwise eligible for services.
9

10 20. Plaintiff's facilities provide an array of services including direct medical,
11 dental and behavioral health care, radiology services, laboratory services, and pharmaceuticals.
12 The services available in an individual community vary based on a number of factors. Many of
13 the communities in Plaintiff's service area are not connected by roads and can only be accessed
14 by boat or small plane. Because of the challenges inherent in accessing services in remote
15 communities, Plaintiff's medical providers who work at larger facilities make regular trips to
16 the smaller, remote clinics to provide specialty services that would not otherwise be available
17 in those villages. Plaintiff provides access to primary and preventive care services as well as
18 urgent and after hours care. Most of the health centers operated by Plaintiff employ behavioral
19 health clinicians and/or Community Family Service workers to provide on-site mental health
20 and substance abuse services.
21

22 21. Plaintiff operates in one of the most isolated regions of the country, and is
23 the sole health care provider in most communities in the service area. For that reason, Plaintiff
24 serves IHS beneficiaries as well as non-beneficiaries. Plaintiff charges according to a sliding
25
26
27

1 scale discounted fee schedule to ensure that its services are available to all clients without
2 regard for the individual's ability to pay.

3 22. The Plaintiff serves high-needs populations with limited resources,
4 including in remote areas where access to other providers may not exist or would require a boat
5 ride or flight. The diversion of funding to address a public health crisis like the opioid
6 epidemic, including associated overhead and administrative costs, can have devastating
7 impacts on the ability of the Plaintiff to provide an adequate level of basic health care and other
8 needed specialty care in these areas, to meet their obligations under the ISDEAA and
9 agreements with the IHS, and to carry out their organizational missions.
10

11 23. The Plaintiff has standing to recover damages incurred because of
12 Defendants' actions and omissions. The Plaintiff has standing to bring all claims pled herein,
13 including, *inter alia*, to bring claims under the federal RICO statutes, pursuant to 18 U.S.C. §
14 1961(3) ("persons" include entities which can hold legal title to property) and 18 U.S.C. §
15 1964 ("persons" have standing).
16

17 B. Manufacturer Defendants
18

19 24. The Manufacturer Defendants are identified below. At all relevant times, the
20 Manufacturer Defendants have packaged, distributed, supplied, sold, placed into the stream of
21 commerce, labeled, described, marketed, advertised, promoted, and purported to warn or
22 purported to inform prescribers and users regarding the benefits and risks associated with the
23 use of prescription opioid drugs. The Manufacturer Defendants, at all times, have
24 manufactured and sold prescription opioids without fulfilling their legal duty to prevent
25 diversion and report suspicious orders.
26
27

1 25. PURDUE PHARMA L.P. is a limited partnership organized under the laws
2 of Delaware. PURDUE PHARMA INC. is a New York corporation with its principal place of
3 business in Stamford, Connecticut. THE PURDUE FREDERICK COMPANY is a Delaware
4 corporation with its principal place of business in Stamford, Connecticut. RHODES
5 PHARMACEUTICALS, L.P. is a limited partnership organized under the laws of Delaware
6 with its principal place of business in Coventry, Rhode Island. RHODES TECHONOLOGIES,
7 INC. is based in Coventry, Rhode Island, and operates as a subsidiary of Purdue Pharma L.P.
8 Purdue Pharma L.P., Purdue Pharma Inc., The Purdue Frederick Company, Rhodes
9 Pharmaceuticals, L.P., and Rhodes Technologies Inc. are referred to collectively as “Purdue.”
10

11 26. Each Purdue entity acted in concert with one another and acted as agents
12 and/or principals of one another in connection with the conduct described herein.
13

14 27. Purdue manufactures, promotes, sells, and distributes opioids such as
15 OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER,¹⁰ and Targiniq ER in the
16 U.S., including Alaska. OxyContin is Purdue’s best-selling opioid. Since 2009, Purdue’s
17 annual sales of OxyContin have fluctuated between \$2.47 billion and \$2.99 billion, up four-
18 fold from its 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire
19 market for analgesic drugs (painkillers).
20

21 28. CEPHALON, INC. is a Delaware corporation with its principal place of
22 business in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (Teva
23 Ltd.) is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In
24 2011, Teva Ltd. acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (Teva
25
26
27

1 USA) is a wholly owned subsidiary of Teva Ltd. and is a Delaware corporation with its principal
2 place of business in Pennsylvania. Teva USA acquired Cephalon, Inc. in October 2011. Teva
3 Pharmaceuticals Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are
4 referred to collectively as “Cephalon.”
5

6 29. Cephalon, Inc. manufactures, promotes, sells and distributes opioids such as
7 Actiq and Fentora in the U.S., including in Alaska. The FDA approved Actiq and Fentora only
8 for the management of breakthrough cancer pain in patients who are tolerant to around-the-
9 clock opioid therapy for their underlying persistent cancer pain. In 2008, Cephalon pleaded
10 guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading
11 promotion of Actiq and two other drugs and agreed to pay \$425 million.
12

13 30. JANSSEN PHARMACEUTICALS, INC. is a Pennsylvania corporation with
14 its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of
15 JOHNSON & JOHNSON (J&J), a New Jersey corporation with its principal place of business in
16 New Brunswick, New Jersey. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-
17 McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen
18 Pharmaceutica, Inc. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known
19 as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of
20 business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as
21 Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business
22 in Titusville, New Jersey. NORAMCO is a Delaware company headquartered in Wilmington,
23 Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active
24
25

26 ¹⁰ Long-acting or extended release (ER or ER/LA) opioids are designed to be taken once or twice daily. Short-acting
27

1 pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital. Janssen
2 Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc.,
3 Noramco, and J&J are referred to collectively as “Janssen”. Upon information and belief, J&J
4 controls the sale and development of Janssen Pharmaceutical’s products and corresponds with
5 the FDA regarding Janssen’s products.
6

7 31. Janssen manufactures, promotes, sells, and distributes drugs in the United
8 States, including in Alaska, including the opioid Duragesic (fentanyl). Until January 2015,
9 Janssen also developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together,
10 Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.
11

12 32. ENDO HEALTH SOLUTIONS INC. is a Delaware corporation with its
13 principal place of business in Malvern, Pennsylvania. ENDO PHARMACEUTICALS INC. is a
14 wholly owned subsidiary of Endo Health Solutions Inc. and is a Delaware corporation with its
15 principal place of business in Malvern, Pennsylvania. ENDO INTERNATIONAL PLC, has
16 global headquarters in Dublin, Ireland and U.S. headquarters in Malvern, Pennsylvania. PAR
17 PHARMACEUTICAL, INC. is a Delaware corporation with its principal place of business
18 located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary
19 of Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc. PAR
20 PHARMACEUTICAL COMPANIES, INC. is a Delaware corporation with its principal place
21 of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par
22 Pharmaceutical Companies, Inc. are collectively referred to as “Par Pharmaceutical.” Par
23 Pharmaceutical was acquired by Endo International plc in September 2015 and is an operating
24
25

26 opioids, also known as immediate release (IR) opioids, last for approximately 4-6 hours.
27

1 company of Endo International plc. Endo Health Solutions Inc., Endo Pharmaceuticals Inc.,
2 Endo International plc, and Par Pharmaceutical are referred to collectively as “Endo.”

3 33. Endo develops, markets, and sells prescription drugs, including the opioids
4 Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States, including in Alaska.
5 Opioids made up roughly \$403 million of Endo’s overall revenues of \$3 billion in 2012. Opana
6 ER yielded \$1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo’s
7 total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone,
8 oxymorphone, hydromorphone, and hydrocodone products in the United States, including in
9 Alaska, by itself, through Par Pharmaceutical and through its subsidiary, Qualitest
10 Pharmaceuticals, Inc.
11

12 34. ALLERGAN PLC is a public limited company incorporated in Ireland with
13 its principal place of business in Dublin, Ireland. ACTAVIS PLC acquired Allergan plc in
14 March 2015, and the combined company changed its name to Allergan PLC in January 2013.
15 Before that, WATSON PHARMACEUTICALS, INC. acquired Actavis, Inc. in October 2012.
16 The combined company changed its name to Actavis, Inc. as of January 2013, and then to
17 Actavis plc in October 2013. WATSON LABORATORIES, INC. is a Nevada corporation with
18 its principal place of business in Corona, California, and is a wholly owned subsidiary of
19 Allergan plc (Allergan Finance, LLC, f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).
20 ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.) is a Delaware corporation with its principal
21 place of business in New Jersey, and was formerly known as WATSON PHARMA, INC.
22 ACTAVIS LLC is a Delaware limited liability company with its principal place of business in
23 Parsippany, New Jersey. Each of these defendants is owned by Allergan plc, which uses them to
24
25
26
27

1 market and sell its drugs in the United States, including in Alaska. Upon information and belief,
2 Allergan plc exercises control over these marketing and sales efforts, and profits from the sale
3 of Allergan/Actavis products ultimately inure to its benefit. Allergan plc, Actavis plc, Actavis,
4 Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc.,
5 and Watson Laboratories, Inc. are referred to collectively as “Actavis.”
6

7 35. Actavis manufactures, promotes, sells, and distributes opioids, including the
8 branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of
9 Duragesic and Opana, in the U.S., including in Alaska.
10

11 36. INSYS THERAPEUTICS, INC. is a Delaware corporation with its principal
12 place of business in Arizona. Insys’s principal product and source of revenue is Subsys, a
13 transmucosal immediate-release formulation (TIRF) of fentanyl. Subsys was approved by the
14 FDA solely for the treatment of breakthrough cancer pain. Insys promotes, sells, and
15 distributes Subsys throughout the United States, including Alaska.
16

17 37. Insys’s founder and owner was recently arrested and charged, along with
18 other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe
19 practitioners to prescribe Subsys and defraud insurance companies. Insys specifically targeted
20 at least one prescriber in Anchorage, Alaska, who was one of the top prescribers of Insys in the
21 United States and whose license was ultimately suspended and then surrendered as a result of
22 an investigation by the Alaska State Medical Board into his opioid prescribing practices.¹¹
23

24 ¹¹ See Linette Lopez, *One company symbolizes everything sickening about the opioid crisis*, Business Insider, Apr.
25 13, 2017, available at <http://www.businessinsider.com/opioid-crisis-and-insys-therapeutics-fentanyl-spray-2017-4>.
26 See also, ProPublica, Prescriber Checkup: Subsys, <https://projects.propublica.org/checkup/drugs/8147> (last visited
27 Aug. 10, 2018) (listing top prescribers of Subsys in the United States, including Dr. Ahmad of Anchorage, Alaska);
ProPublica, Dollars for Docs: Talk With Your Doctor - Mahmood Ahmad,

1 38. MALLINCKRODT, PLC is an Irish public limited company headquartered in
2 Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.
3 MALLINCKRODT, LLC, is a limited liability company organized and existing under the laws of
4 the State of Delaware. Mallinckrodt, LLC is a wholly-owned subsidiary of Mallinckrodt, plc.
5 SPECGX LLC is a Delaware limited liability company with its headquarters in Clayton,
6 Missouri and is a wholly-owned subsidiary of Mallinckrodt plc. Mallinckrodt, plc,
7 Mallinckrodt, LLC, and SpecGX LLC are collectively referred to as “Mallinckrodt.”

9 39. Mallinckrodt manufactures, markets, and sells drugs in the United States and
10 Alaska, including generic oxycodone. Mallinckrodt is the largest U.S. supplier of opioid pain
11 medications and among the top ten generic pharmaceutical manufacturers in the United States,
12 based on prescriptions. Mallinckrodt is one of the largest manufacturers of generic oxycodone.
13 In July 2017, Mallinckrodt agreed to pay \$35 million to settle allegations brought by the
14 Department of Justice that it failed to detect and notify the DEA of suspicious orders of
15 controlled substances.
16

17 40. ABBOTT LABORATORIES is an Illinois corporation with its principal
18 place of business in Abbott Park, Illinois. Defendant, ABBOTT LABORATORIES, INC., is an
19 Illinois corporation with its principal place of business in Abbott Park, Illinois. ABBOTT
20 LABORATORIES and ABBOTT LABORATORIES, INC. are referred to collectively as
21 “Abbott.”
22

23 41. Abbott was primarily engaged in the promotion and distribution of opioids
24 nationally due to a co-promotional agreement with Defendant Purdue. Abbott promoted and
25

26

27 <https://projects.propublica.org/docdollars/doctors/print/128721> (last visited Aug. 10, 2018) (listing payments from
28

1 distributed these opioids in the United States, including Alaska. Pursuant to an agreement with
2 Purdue, between 1996 and 2006, Abbott actively promoted, marketed, and distributed Purdue's
3 opioid products.

4 42. Abbott, as part of the co-promotional agreement, helped make OxyContin
5 into the largest selling opioid in the nation. Under the co-promotional agreement with Purdue,
6 the more Abbott generated in sales, the higher the reward. Specifically, Abbott received twenty-
7 five to thirty percent (25-30%) of all net sales for prescriptions written by doctors its sales force
8 called on. This agreement was in operation from 1996-2002, following which Abbott continued
9 to receive a residual payment of six percent (6%) of net sales up through at least 2006.
10

11 43. With Abbott's help, sales of OxyContin went from a mere \$49 million in its
12 first full year on the market to \$1.6 billion in 2002. Over the life of the co-promotional
13 agreement, Purdue paid Abbott nearly half a billion dollars. Abbott and Purdue's conspiring
14 with pharmacy benefits managers to drive opioid use is well established.
15

16 44. As described in an October 28, 2016 article from Psychology Today entitled
17 *America's Opioid Epidemic:*
18

19 Abbott and Purdue actively misled prescribers about the strength and
20 safety of the painkiller [OxyContin]. To undermine the policy of
21 requiring prior authorization, they offered lucrative rebates to
22 [intermediaries] and other pharmacy benefits managers, on condition
23 that they eased availability of the drug and lowered co-pays. The
24 records were part of a case brought by the state of West Virginia
25 against both drug makers alleging inappropriate and illegal marketing
26 of the drug as a cause of widespread addiction.

27

Insys to Dr. Ahmad).

COMPLAINT - 15

1 One reason the documents are so troubling is that, in public at least,
2 the drug maker was carefully assuring authorities that it was working
3 with state authorities to curb abuse of OxyContin. Behind the scenes,
4 however, as one Purdue official openly acknowledged, the drug maker
was “working with Medco (PBM) [now Express Scripts] to try to
make parameters [for prescribing] less stringent.”¹²

5 45. AMNEAL PHARMACEUTICALS, INC. is a Delaware business entity with
6 its principal place of business in New Jersey. Amneal Pharmaceuticals, Inc. was created when
7 AMMEAL PHARMACEUTICALS, LLC merged with Impax. The merger was approved in
8 2018. Amneal Pharmaceuticals was headquartered in New Jersey. Amneal Pharmaceuticals,
9 Inc., and Amneal Pharmaceuticals LLC, are collectively referred to as “Amneal.” Amneal
10 manufactures, promotes, sells, and distributes generic opioid products in the United States,
11 including Alaska.

13 46. KVK-Tech, Inc. (KVK) is a Pennsylvania business entity with its principal
14 place of business in Pennsylvania. KVK manufactures, promotes, sells, and distributes generic
15 opioid products in the United States, including in Alaska.

17 47. Collectively, Purdue, Cephalon, Janssen, Endo, Actavis, Insys, Mallinckrodt,
18 Amneal, and KVK are the “Manufacturer Defendants.”

19 C. Distributor Defendants

20 48. Distributor Defendants are identified below. At all relevant times, the
21 Distributor Defendants have distributed, supplied, sold, and placed into the stream of
22 commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug
23 distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The
24

25
26 ¹² Christopher Lane, *America's Opioid Epidemic – Court released documents show drug makers blocked efforts to*
27 *curb prescribing*, Psychology Today, Oct. 28, 2016, <https://www.psychologytoday.com/blog/side->

1 Distributor Defendants universally failed to comply with federal law. Plaintiff alleges the
2 unlawful conduct by the Distributor Defendants is responsible for the volume of prescription
3 opioids plaguing the United States, including Alaska.

4 49. CARDINAL HEALTH, INC. is a publicly traded company incorporated
5 under the laws of Ohio and with a principal place of business in Ohio. CARDINAL HEALTH
6 110, LLC., is based in Dublin, Ohio, and operates as a subsidiary of Cardinal Health, Inc.
7 Cardinal Health, Inc., and Cardinal Health 110, LLC, are referred to collectively as “Cardinal.”
8 During all relevant times, Cardinal has distributed substantial amounts of prescription opioids
9 to providers and retailers in Alaska and held a business and/or professional license in the State.
10

11 50. AMERISOURCEBERGEN CORPORATION (AmerisourceBergen) is a
12 publicly traded company incorporated under the laws of Delaware and with a principal place of
13 business in Pennsylvania. During all relevant times, AmerisourceBergen has distributed
14 substantial amounts of prescription opioids to providers and retailers in Alaska and held a
15 business and/or professional license in the State.
16

17 51. MCKESSON CORPORATION (McKesson) is a publicly traded company
18 incorporated under the laws of Delaware and with a principal place of business in San
19 Francisco, California. During all relevant times, McKesson has distributed substantial amounts
20 of prescription opioids to providers and retailers in Alaska and held a business and/or
21 professional license in the State.
22

23 52. ANDA, INC. is a Florida corporation with its principal office located in
24 Weston, Florida. ANDA PHARMACEUTICALS, INC. was founded in 1992 and is based in
25

26 [effects/201610/america-s-opioid-epidemic](#)
27

1 Groveport, Ohio. Anda, Inc. and Anda, Pharmaceuticals Inc. are referred to collectively as
2 “Anda”. In October 2016, Defendant Teva acquired Anda from Allergan plc (i.e., Defendant
3 Actavis), for \$500 million in cash. At all times relevant, Anda distributed prescription opioids
4 throughout the United States, including in Alaska.
5

6 53. HENRY SCHEIN, INC. is incorporated in Delaware, with its principal place
7 of business in Melville, New York. Henry Schein, Inc. describes its business as providing a
8 comprehensive product and services offerings to integrated health systems, designed
9 specifically for and focused exclusively on, the non-acute care space. Henry Schein, Inc.
10 distributes, among other things, branded and generic pharmaceuticals to customers that include
11 dental practitioners, dental laboratories, animal health practices and clinics, and office-based
12 medical practitioners, ambulatory surgery centers, and other institutions. HENRY SCHEIN
13 MEDICAL SYSTEMS, INC. (Henry Schein Medical) is a subsidiary of Henry Schein, Inc. that
14 provides practice management, electronic medical records, and document management for
15 medical groups. Henry Schein, Inc. and Henry Schein Medical Systems Inc. are referred to
16 collectively as “Henry Schein.”
17
18

19 54. In November of 2014, Henry Schein Medical and Cardinal Health entered
20 into a strategic partnership, which consolidated Cardinal Health’s physician office sales
21 organization into Henry Schein Medical. Henry Schein took responsibility for serving
22 physician offices, and through its “symbiotic” arrangement with Cardinal Health, gained access
23 to over 25,000 physical offices as customer locations. As a result of this agreement, Henry
24 Schein Medical added more than \$300 million in annual sales. At all relevant times, Henry
25 Schein was in the business of distributing, and redistributing, pharmaceutical products to
26
27

1 consumers within the State of Alaska.

2 55. In 2015, Henry Schein reported that its sales reached a record \$10.4 billion
3 and that it had grown at a compound annual rate of approximately 16 percent since becoming a
4 public company in 1995. Overall, it is the world's largest provider of health care products and
5 services to office-based dental, animal health, and medical practitioners.
6

7 56. Collectively, Cardinal, AmerisourceBergen, McKesson, Anda, and Henry
8 Schein are the "Distributor Defendants".

9 57. The data that reveals and/or confirms the identity of each wrongful opioid
10 distributor and the extent of their activity in Alaska is hidden from public view in the DEA's
11 confidential ARCOS database. *See Madel v. U.S. Dep't of Justice*, 784 F.3d 448, 451 (8th Cir.
12 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data
13 necessary to identify with specificity the transactions that will form the evidentiary basis for
14 the claims asserted herein. *See id.* at 452-53.
15

16 58. Collectively, AmerisourceBergen, Cardinal, and McKesson dominate 85% of
17 the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500
18 corporations listed on the New York Stock Exchange whose principal business is the
19 nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal*
20 *Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal, McKesson, and
21 AmerisourceBergen predecessors). Anda is the fourth largest distributor of generic
22 pharmaceuticals in the United States.
23
24
25
26
27

1 D. John and Jane Does 1-100, inclusive

2 59. In addition to Defendants, the true names, roles, and/or capacities in the
3 wrongdoing alleged herein of Defendants named John and Jane Does 1 through 100, inclusive,
4 are currently unknown to Plaintiff, and thus are named Defendants under fictitious names as
5 permitted by the Rules of this Court. Plaintiff will amend this Complaint and identify their true
6 identities and their involvement in the wrongdoing at issue, as well as the specific causes of
7 action asserted against them when they become known.
8

9 III. JURISDICTION AND VENUE

10 60. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because
11 this action presents a federal question. This Court has supplemental jurisdiction over the state
12 law causes of action under 28 U.S.C. § 1367 because the state law claims are part of the same
13 case or controversy.
14

15 61. This Court independently has subject-matter jurisdiction over Plaintiff's
16 state law claims under 28 U.S.C. § 1332(a)(2), because the matter in controversy exceeds the
17 sum of \$75,000 and no Defendant is a citizen of the same state as the Plaintiff.
18

19 62. This Court has personal jurisdiction over all Defendants because all
20 Defendants have substantial contacts and business relationships with the State of Alaska, and
21 have purposefully availed themselves of business opportunities within the State of Alaska,
22 including by marketing, distributing, or selling prescription opioids within the State of Alaska.
23

24 63. This Court also has personal jurisdiction over all of the defendants under 18
25 U.S.C. § 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants
26 where the "ends of justice" require national service and Plaintiff demonstrates national
27

1 contacts. Here, the interests of justice require that Plaintiff be allowed to bring all members of
2 the nationwide RICO enterprise before the court in a single trial. *See, e.g., Iron Workers Local*
3 *Union No. 17 Ins. Fund v. Philip Morris Inc.*, 23 F. Supp. 2d 796 (N.D. Ohio 1998); *Butcher's*
4 *Union Local No. 498, United Food & Commercial Workers v. SDC Inv., Inc.*, 788 F.2d 535,
5 539 (9th Cir. 1986).

6
7 64. Venue is proper in this Court under 28 U.S.C. § 1391(b) and 18 U.S.C. §
8 1965 because a substantial part of the events or omissions giving rise to this action occurred in
9 this judicial district and because all defendants are subject to this Court's exercise of personal
10 jurisdiction.

11 IV. ADDITIONAL FACTUAL ALLEGATIONS

12 A. Background

13
14 65. The term "opioid" includes all drugs derived from the opium poppy. The
15 United States Food and Drug Administration (FDA) describes opioids as follows: "Prescription
16 opioids are powerful pain-reducing medications that include prescription oxycodone,
17 hydrocodone, and morphine, among others, and have both benefits as well as potentially
18 serious risks." These medications can help manage pain when prescribed for the right condition
19 and when used properly. But when misused or abused, they can cause serious harm, including
20 addiction, overdose, and death.¹³

21
22 66. Prescription opioids with the highest potential for addiction are listed under
23 Schedule II of the Controlled Substances Act. This includes non-synthetic opium derivatives
24 (such as codeine and morphine, also known generally as "opiates"), partially synthetic
25
26
27

1 derivatives (such as hydrocodone and oxycodone), and fully synthetic derivatives (such as
2 fentanyl and methadone).

3 67. Historically, opioids were considered too addictive and debilitating for the
4 treatment of chronic pain, like back pain, migraines, and arthritis. According to Dr. Caleb
5 Alexander, director of Johns Hopkins University's Center for Drug Safety and Effectiveness,
6 "[opioids] have very, very high inherent risks . . . and there's no such thing as a fully safe
7 opioid."¹⁴
8

9 68. Opioids also tend to induce tolerance, whereby a person who uses opioids
10 repeatedly over time no longer responds to the drug as strongly as before, thus requiring a
11 higher dose to achieve the same effect. This tolerance contributes to the high risk of overdose
12 during a relapse.
13

14 69. Before the 1990s, generally accepted standards of medical practice dictated
15 that opioids should only be used short-term for acute pain, pain relating to recovery from
16 surgery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids
17 improved patients' ability to overcome pain and function, coupled with evidence of greater
18 pain complaints as patients developed tolerance to opioids over time, and the serious risk of
19 addiction and other side effects, the use of opioids for chronic pain was discouraged or
20 prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.
21
22

23 ¹³ See U.S. Food & Drug Admin., U.S. Dep't of Health and Human Servs., *Opioid Medications*,
24 <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm337066.htm> (last updated Feb. 15, 2018).

25 ¹⁴ Matthew Perrone, et al., *Drugmakers push profitable, but unproven, opioid solution*, The Center for Public
26 Integrity, Dec. 15, 2016, available at [https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution)
27 [profitable-unproven-opioid-solution](https://www.publicintegrity.org/2016/12/15/20544/drugmakers-push-profitable-unproven-opioid-solution) (last accessed Aug. 10, 2018).

1 B. The Manufacturer Defendants engaged in false, deceptive, and unfair marketing
2 of opioids in order to create, and profit from, an inflated opioid market

3 70. To take advantage of the much larger and more lucrative market for chronic
4 pain patients, the Manufacturer Defendants actively worked to change medical thinking about
5 opioids.¹⁵

6 71. To that end, each Manufacturer Defendant developed a well-funded
7 marketing scheme based on deception to persuade doctors, health care providers, and patients
8 that opioids can and should be used for treatment of chronic pain, resulting in opioid treatment
9 for a far larger group of patients who are much more likely to become addicted. In connection
10 with this scheme, each Manufacturer Defendant spent, and continue to spend, millions of
11 dollars on promotional activities and materials that falsely deny or minimize the risks of
12 opioids while overstating the benefit of using them for chronic pain.
13

14 72. The deceptive marketing schemes included, among others, (1) false or
15 misleading direct, branded advertisements; (2) false or misleading direct-to-physician
16 marketing, also known as “detailing;” (3) false or misleading materials, speaker programs,
17 webinars, and brochures; and (4) false or misleading unbranded advertisements or statements
18 by purportedly neutral third parties that were really designed and distributed by the
19 Manufacturer Defendants. In addition to using third parties to disguise the source of their
20 misinformation campaign, the Manufacturer Defendants also retained the services of certain
21 physicians, known as “key opinion leaders” or “KOLs” to convince both doctors and patients
22 that opioids were safe for the treatment of chronic pain.
23
24

25
26 ¹⁵ See Harriet Ryan, et al., ‘You want a description of hell?’ OxyContin’s 12-hour problem, L.A. Times, May 5,
27 2016, available at <http://www.latimes.com/projects/oxycontin-part1> (last accessed Aug. 10, 2018).

1 73. As part of these marketing efforts the Manufacturer Defendants have made
2 false and misleading claims, contrary to the language on their drugs' labels regarding the risks
3 of using their drugs that: (1) downplayed the seriousness of addiction; (2) created and
4 promoted the concept of "pseudoaddiction" when signs of actual addiction began appearing
5 and advocated that the signs of addiction should be treated with more opioids; (3) exaggerated
6 the effectiveness of screening tools to prevent addiction; (4) claimed that opioid dependence
7 and withdrawal are easily managed; (5) denied the risks of higher dosages; and (6) exaggerated
8 the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. The
9 Manufacturer Defendants have also falsely touted the benefits of long-term opioid use,
10 including the supposed ability of opioids to improve function and quality of life, even though
11 there was no scientifically reliable evidence to support the Manufacturer Defendants' claims.
12

14 74. The Manufacturer Defendants have intentionally disseminated these
15 common messages to reverse the medical understanding and public conceptions of opioids and
16 risks of opioid use. They disseminated these messages directly, through their sales
17 representatives, in speaker groups led by physicians the Manufacturer Defendants recruited for
18 their support of the Manufacturer Defendants' marketing messages, through unbranded
19 marketing and through industry-funded Front Groups. The messages were intended to, and did,
20 reach throughout the medical community within the United States, including Alaska, in order
21 to influence medical thinking and prescribing behavior nationwide.
22

24 75. These statements were not only unsupported by or contrary to the scientific
25 evidence, they were also contrary to pronouncements by and guidance from the FDA and the
26 Center for Disease Control (CDC) based on that same evidence.
27

1 76. The Manufacturer Defendants began their marketing schemes decades ago
2 and continue them today.

3 77. As discussed herein, the 2016 Guideline for Prescribing Opioids for Chronic
4 Pain, published by the CDC, makes it patently clear that the Manufacturer Defendants'
5 schemes were and continue to be deceptive.¹⁶
6

7 78. On information and belief, as a part of their deceptive marketing scheme,
8 the Manufacturer Defendants identified and targeted susceptible prescribers and vulnerable
9 patient populations in the United States, including in Alaska, and in particular in the
10 geographic area in Alaska served by the Plaintiff.
11

12 79. For example, on information and belief, the Manufacturer Defendants
13 focused their deceptive marketing on primary care doctors, who were more likely to treat
14 chronic pain patients and prescribe them drugs, but were less likely to be schooled in treating
15 pain and the risks and benefits of opioids and therefore more likely to accept the Manufacturer
16 Defendants' misrepresentations.
17

18 80. On information and belief, the Manufacturer Defendants also targeted
19 vulnerable patient populations like the elderly and veterans, injured workers, and cancer
20 patients, who tend to suffer from chronic pain.

21 81. The Manufacturer Defendants targeted these vulnerable patients even
22 though the risks of long-term opioid use were significantly greater for them. For example, the
23 2016 CDC Guideline observed that existing evidence showed that elderly patients taking
24

25 ¹⁶ Deborah Dowell, et al., *CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016*, 65
26 *Morbidity & Mortality Wkly. Rep.* 1 (2016) [hereinafter "2016 CDC Guideline"], available at
27 <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

1 opioids suffer from elevated fall and fracture risks, greater risk of hospitalization, and
2 increased vulnerability to adverse drug effects and interactions. The Guideline therefore
3 concluded that there are special risks of long-term opioid use for elderly patients and
4 recommended that doctors use “additional caution and increased monitoring”¹⁷ to minimize the
5 risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use
6 anti-anxiety drugs (benzodiazepines) for posttraumatic stress disorder, which interact
7 dangerously with opioids.

8
9 82. To increase the impact of their deceptive marketing schemes, on information
10 and belief, the Manufacturer Defendants coordinated and created unified marketing plans to
11 ensure that their messages were consistent and effective across all their marketing efforts.
12

13 83. Defendants’ efforts have been wildly successful. Opioids are now the most
14 prescribed class of drugs. Globally, opioid sales generated \$11 billion in revenue for drug
15 companies in 2010 alone; sales in the United States have exceeded \$8 billion in revenue
16 annually since 2009.¹⁸ In Alaska, two of the top ten most prescribed drugs are opioids.¹⁹
17

18 84. In an open letter to the nation’s physicians in August 2016, the then-U.S.
19 Surgeon General expressly connected this “urgent health crisis” to “heavy marketing of opioids
20

21 ¹⁷ *Id.* at 27.

22 ¹⁸ See Katherine Eban, *OxyContin: Purdue Pharma’s painful medicine*, Fortune, Nov. 9, 2011, available at
<http://fortune.com/2011/11/09/oxycontin-purdue-pharmas-painful-medicine/>; David Crow, *Drugmakers hooked on*
\$10bn opioid habit, Fin. Times (Aug. 10, 2016), available at [https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95)
23 [a121aa8abd95](https://www.ft.com/content/f6e989a8-5dac-11e6-bb77-a121aa8abd95).

24 ¹⁹ From March 2017 to February 2018, the top prescriptions included: #1. Hydrocodone/acetaminophen – pain
medication and #4. Oxycodone/acetaminophen – pain medication. Kylie Walsh, *Most frequently prescribed*
medication in Alaska is an opioid, State of Reform, Mar 27, 2018, [https://stateofreform.com/featured/2018/03/most-](https://stateofreform.com/featured/2018/03/most-frequently-prescribed-medication-in-alaska-is-an-opioid/)
25 [frequently-prescribed-medication-in-alaska-is-an-opioid/](https://stateofreform.com/featured/2018/03/most-frequently-prescribed-medication-in-alaska-is-an-opioid/) (last visited Aug. 10, 2018).
26
27

1 to doctors. . . [m]any of [whom] were even taught – incorrectly – that opioids are not addictive
2 when prescribed for legitimate pain.”²⁰

3 85. The Manufacturer Defendants intentionally continued their conduct, as
4 alleged herein, with knowledge that such conduct was creating the opioid epidemic and
5 causing the harms and damages alleged herein.
6

- 7 1. The Manufacturer Defendants’ used various types of Marketing Activities to
8 disseminate false and misleading statements

9 86. The Manufacturer Defendants spread their false and deceptive statements by
10 marketing their branded opioids directly to doctors and patients throughout the United States.
11 They also deployed seemingly unbiased and independent third parties that they controlled to
12 spread their false and deceptive statements about the risks and benefits of opioids for the
13 treatment of chronic pain throughout the United States, including Alaska and the geographic
14 area in Alaska served by the Plaintiff.
15

16 *a. Direct Marketing*

17 87. The Manufacturer Defendants’ direct marketing of opioids generally
18 proceeded on two tracks: advertising campaigns and direct-to-physician marketing.
19

20 88. First, each Manufacturer Defendant conducted and continues to conduct
21 advertising campaigns touting the purported benefits of their branded drugs. For example, upon
22 information and belief, the Manufacturer Defendants spent more than \$14 million on medical
23 journal advertising of opioids in 2011, nearly triple what they spent in 2001.
24

25 ²⁰ Murthy, *supra* note 9.
26
27

1 89. A number of the Manufacturer Defendants’ branded ads deceptively
2 portrayed the benefits of opioids for chronic pain. Some examples include:

3 a. Endo, on information and belief, has distributed and made available on its
4 website opana.com a pamphlet promoting Opana ER with photographs
5 depicting patients with physically demanding jobs like construction worker
6 and chef, misleadingly implying that the drug would provide long-term pain
7 relief and functional improvement.
8

9 b. On information and belief, Purdue also ran a series of ads, called “Pain
10 vignettes,” for OxyContin in 2012 in medical journals. These ads featured
11 chronic pain patients and recommended OxyContin for each. One ad
12 described a “54-year-old writer with osteoarthritis of the hands” and implied
13 that OxyContin would help the writer work more effectively.
14

15 90. Although Endo and Purdue agreed in late 2015 and 2016 to halt these
16 misleading representations in New York, they continued to disseminate them elsewhere.
17

18 91. The direct advertising disseminated by the Manufacturer Defendants did not
19 disclose studies that were unfavorable to their products, nor did they disclose that the lack of
20 clinical evidence to support many of their claims.

21 *b. “Detailing” and speaker programs*

22 92. Second, each Manufacturer Defendant promoted the use of opioids for
23 chronic pain through “detailers”—sophisticated and specially trained sales representatives who
24 visited individual doctors and medical staff in their offices—and small group speaker
25 programs.
26
27

1 93. The Manufacturer Defendants invested heavily in promoting the use of
2 opioids for chronic pain through detailers and small group speaker programs.

3 94. Each Defendant devoted massive resources to direct sales contacts with
4 doctors. Upon information and belief, the Manufacturer Defendants spent in excess of \$168
5 million in 2014 alone on detailing branded opioids to doctors, more than twice what they spent
6 on detailing in 2000.

7 95. On information and belief, these detailers have spread and continue to
8 spread misinformation regarding the risks and benefits of opioids to hundreds of thousands of
9 doctors, including doctors in Alaska. For example, on information and belief, the Manufacturer
10 Defendants' detailers, over the past two years, continue to falsely and misleadingly:
11

- 12 a. Describe the risk of addiction as low or fail to disclose the risk of addiction;
- 13 b. Describe their opioid products as “steady state”—falsely implying that these
14 products are less likely to produce the highs and lows that fuel addiction—
15 or as less likely to be abused or result in addiction;
- 16 c. Tout the effectiveness of screening or monitoring patients as a strategy for
17 managing opioid abuse and addiction;
- 18 d. State that there is no maximum dose and that doctors can safely increase
19 doses without disclosing the significant risks to patients at higher doses;
- 20 e. Promote the fictional concept of “pseudoaddiction” (this concept is
21 described in paragraphs 114 and 149-51, *infra*);
- 22 f. State that patients would not experience withdrawal if they stopped using
23 their opioid products;
- 24
- 25
- 26
- 27

1 g. State that their opioid products are effective for chronic pain without
2 disclosing the lack of evidence for the effectiveness of long-term opioid use;
3 and

4 h. State that abuse-deterrent formulations are tamper- or crush-resistant and
5 harder to abuse or misuse.
6

7 96. Because these detailers must adhere to scripts and talking points drafted by
8 the Manufacturer Defendants, it can be reasonably inferred that most, if not all, of the
9 Manufacturer Defendants' detailers made and continue to make these misrepresentations to the
10 thousands of doctors they have visited and continue to visit. The Manufacturer Defendants
11 have not corrected this misinformation.
12

13 97. The Manufacturer Defendants' detailing to doctors was highly effective in
14 the national proliferation of prescription opioids. On information and belief, the Manufacturer
15 Defendants used sophisticated data mining and intelligence to track and understand the rates of
16 initial prescribing and renewal by individual doctors, allowing specific and individual
17 targeting, customizing, and monitoring of their marketing.
18

19 98. The Manufacturer Defendants also identified doctors to serve, for payment
20 and other remuneration, on their speakers' bureaus and to attend programs with speakers and
21 meals paid for by the Manufacturer Defendants. These speakers gave the false impression that
22 they were providing unbiased and medically accurate presentations when they were, in fact,
23 presenting a script prepared by the Manufacturer Defendants. On information and belief, these
24 presentations conveyed misleading information, omitted material information, and failed to
25
26
27

1 correct the Manufacturer Defendants’ prior misrepresentations about the risks and benefits of
2 opioids.

3 99. Each Manufacturer Defendant devoted and continues to devote massive
4 resources to direct sales contacts with doctors.

5
6 100. Marketing impacts prescribing habits, with face-to-face detailing having the
7 greatest influence. On information and belief, physicians who prescribe opioids frequently are
8 generally more likely to have received a detailing visit. In some instances, physicians who
9 prescribed opioids only infrequently received a detailing visit from a Manufacturer
10 Defendant’s detailer, and then prescribed only that Manufacturer Defendant’s opioid products.

11
12 101. The FDA has cited at least one Manufacturer Defendant for deceptive
13 promotions by its detailers and direct-to-physician marketing. In 2010, the FDA notified
14 Actavis that certain brochures distributed by Actavis were “false or misleading because they
15 omit and minimize the serious risks associated with the drug, broaden and fail to present the
16 limitations to the approved indication of the drug, and present unsubstantiated superiority and
17 effectiveness claims.” The FDA also found that “[t]hese violations are a concern from a public
18 health perspective because they suggest that the product is safer and more effective than has
19 been demonstrated.”²¹

20
21 *c. Unbranded advertising disseminated by seemingly independent third*
22 *parties*

23 102. The Manufacturer Defendants also deceptively marketed opioids through
24 unbranded advertising—i.e., advertising that promotes opioid use generally but does not name
25
26
27

1 a specific opioid. This advertising was ostensibly created and disseminated by independent
2 third parties. Yet, by funding, directing, reviewing, editing, and distributing this unbranded
3 advertising, the Manufacturer Defendants coordinated and controlled the deceptive messages
4 disseminated by these third parties and acted in concert with them to falsely and misleadingly
5 promote opioids for the treatment of chronic pain.
6

7 103. The Manufacturer Defendants marketed opioids through third-party,
8 unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to
9 and typically is not reviewed by the FDA. The Manufacturer Defendants also used third-party,
10 unbranded advertising to give the false appearance that the deceptive messages came from an
11 independent and objective source. Like tobacco companies, the Manufacturer Defendants used
12 third parties that they funded, directed, and controlled to carry out and conceal their scheme to
13 deceive doctors and patients about the risks and benefits of long-term opioid use for chronic
14 pain.
15

16 104. The Manufacturer Defendants' deceptive unbranded marketing often
17 contradicted what they said in their branded materials reviewed by the FDA.
18

19 105. The Manufacturer Defendants also spoke through a small circle of doctors—
20 the KOLs—who, upon information and belief, were selected, funded, and elevated by the
21 Manufacturer Defendants because their public positions supported the use of opioids to treat
22 chronic pain.
23

24 ²¹ Letter from Thomas Abrams, Director, Div. of Drug Marketing, Advertising & Communications, U.S. Food &
25 Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), *available at*
<http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf>.
26
27

1 106. Through their use of KOLs and strategic placement of these KOLs
2 throughout every critical distribution channel of information within the medical community,
3 the Manufacturer Defendants were able to exert control of each of these modalities through
4 which doctors receive their information.

5
6 107. Pro-opioid doctors are one of the most important avenues that the
7 Manufacturer Defendants use to spread their false and misleading statements about the risks
8 and benefits of long-term opioid use. The Manufacturer Defendants know that doctors rely
9 heavily and more uncritically on their peers for guidance, and KOLs provide the false
10 appearance of unbiased and reliable support for chronic opioid therapy.

11
12 108. For example, the New York Attorney General (“NY AG”) found in its
13 settlement with Purdue that through March 2015, the Purdue website “In the Face of Pain”
14 failed to disclose that doctors who provided testimonials on the site were paid by Purdue,²² and
15 concluded that Purdue’s failure to disclose these financial connections potentially misled
16 consumers regarding the objectivity of the testimonials.

17
18 109. Pro-opioid KOLs have admitted to making false claims about the
19 effectiveness of opioids. Dr. Russell Portenoy received research support, consulting fees, and
20 other compensation from Cephalon, Endo, Janssen, and Purdue, among others. Dr. Portenoy
21 admitted that he “gave innumerable lectures . . . about addictions that weren’t true.” His
22 lectures falsely claimed that fewer than 1 percent of patients would become addicted to
23 opioids. Dr. Portenoy admitted that the primary goal was to “destigmatize” opioids, and he
24

25 ²² See New York State Office of the Att’y Gen., *A.G. Schneiderman Announces Settlement with Purdue Pharma*
26 *That Ensures Responsible and Transparent Marketing Of Prescription Opioid Drugs By The Manufacturer* (Aug.

1 conceded, “[d]ata about the effectiveness of opioids does not exist.” According to Dr.
2 Portenoy, “Did I teach about pain management specifically about opioid therapy, in a way that
3 reflects misinformation? Well,. . . I guess I did.” Dr. Portenoy admitted that “[i]t was clearly
4 the wrong thing to do.”²³

5
6 110. Dr. Portenoy also made frequent media appearances promoting opioids and
7 spreading misrepresentation, such as his claim that “the likelihood that the treatment of pain
8 using an opioid drug which is prescribed by a doctor will lead to addiction is extremely low.”
9 He appeared on Good Morning America in 2010 to discuss the use of opioids long-term to treat
10 chronic pain. On this widely watched program, broadcast across the country, Dr. Portenoy
11 claimed: “Addiction, when treating pain, is distinctly uncommon. If a person does not have a
12 history, a personal history, of substance abuse, and does not have a history in the family of
13 substance abuse, and does not have a very major psychiatric disorder, most doctors can feel
14 very assured that the person is not going to become addicted.”²⁴

15
16 111. Another KOL, Dr. Lynn Webster, was the co-founder and Chief Medical
17 Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City,
18 Utah. Dr. Webster was President of the American Academy of Pain Medicine (AAPM) in
19 2013. He is a Senior Editor of Pain Medicine, the same journal that published Endo special
20 advertising supplements touting Opana ER. Dr. Webster was the author of numerous
21 Continuing Medical Education or CMEs sponsored by Cephalon, Endo and Purdue. At the
22
23

24 20, 2015), [https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-](https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent)
25 [responsible-and-transparent](https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-purdue-pharma-ensures-responsible-and-transparent) (last accessed Feb. 27, 2018).

26 ²³ Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall St. J., Dec. 17, 2012,
27 available at <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604> (last accessed
Aug. 10, 2018).

1 same time, Dr. Webster was receiving significant funding from the Manufacturer Defendants
2 (including nearly \$2 million from Cephalon).

3 112. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five-
4 question, one-minute screening tool relying on patient self-reports that purportedly allows
5 doctors to manage the risk that their patients will become addicted to or abuse opioids.²⁵ The
6 claimed ability to pre-sort patients likely to become addicted is an important tool in giving
7 doctors confidence to prescribe opioids long-term, and, for this reason, references to screening
8 appear in various industry supported guidelines. Versions of Dr. Webster's Opioid Risk Tool
9 appear on, or are linked to, websites run by Endo, Janssen and Purdue. Unaware of the flawed
10 science and industry bias underlying this tool, certain states and public entities have
11 incorporated the Opioid Risk Tool into their own guidelines, indicating, also, their reliance on
12 the Manufacturer Defendants and those under their influence and control.

15 113. In 2011, Dr. Webster presented via webinar a program sponsored by Purdue
16 entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." On information
17 and belief, Dr. Webster recommended the use of risk screening tools, urine testing and patient
18 agreements as a way to prevent "overuse of prescriptions" and "overdose deaths."²⁶

20 114. Dr. Webster was a leading proponent of the concept of "pseudoaddiction,"
21 the notion that addictive behaviors should be seen not as warnings that a patient was addicted
22 to the drug, but as indications of undertreated pain. In Dr. Webster's description, when a
23

24 ²⁴ Good Morning America (ABC television broadcast Aug. 30, 2010).

25 ²⁵ <https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf>

26 ²⁶ See Emerging Solutions in Pain, *Managing Patient's Opioid Use: Balancing the Need and the Risk*,
27 http://www.emergingsolutionsinpain.com/ce-education/opioidmanagement?option=com_continued&view=frontmatter&Itemid=303&course=209 (last visited Aug. 10, 2018).

1 patient presented such behaviors the only way to differentiate the two was to *increase the*
2 *patient's dose of opioids*. As he and co-author Beth Dove wrote in their 2007 book Avoiding
3 Opioid Abuse While Managing Pain—a book that is still available online—when faced with
4 signs of aberrant behavior, increasing the dose “in most cases . . . should be the clinician’s first
5 response.”²⁷ Upon information and belief, Endo distributed this book to doctors. Years later,
6 Dr. Webster reversed himself, acknowledging that “[pseudoaddiction] obviously became too
7 much of an excuse to give patients more medication.”²⁸

9 115. The Manufacturer Defendants cited and promoted favorable studies or
10 articles by their KOLs. By contrast, Manufacturer Defendants did not support, acknowledge, or
11 disseminate publications of doctors unsupportive or critical of chronic opioid therapy.

13 116. On information and belief, the Manufacturer Defendants also entered into
14 arrangements with seemingly unbiased and independent patient and professional organizations
15 to promote opioids for the treatment of chronic pain. Under the direction and control of the
16 Manufacturer Defendants, these “Front Groups”—which include, but are not limited to, the
17 American Pain Foundation (APF) (of which Dr. Portenoy was a member) and the AAPM—
18 generated treatment guidelines, unbranded materials, and programs that favored chronic opioid
19 therapy. The evidence did not support these guidelines, materials, and programs at the time
20 they were created, and the scientific evidence does not support them today. Indeed, they stand
21 in marked contrast to the 2016 CDC Guideline.
22

24 ²⁷ Lynn R. Webster & Beth Dove, *Avoiding Opioid Abuse While Managing Pain* at 59 (2007).

25 ²⁸ John Fauber, *Painkiller Boom Fueled by Networking*, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012,
26 <http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/>.

1 117. The Manufacturer Defendants worked together, through Front Groups, to
2 spread their deceptive messages about the risks and benefits of long-term opioid therapy.

3 118. On information and belief, these Front Groups also assisted the
4 Manufacturer Defendants by responding to negative articles, by advocating against regulatory
5 or legislative changes that would limit opioid prescribing in accordance with the scientific
6 evidence, and by conducting outreach to vulnerable patient populations targeted by the
7 Manufacturer Defendants.
8

9 119. These Front Groups depended on the Manufacturer Defendants for funding
10 and, in some cases, for survival. A recent U.S. Senate Homeland Security and Governmental
11 Affairs Committee Minority Staff Report reported that Purdue, Janssen, Insys, and other
12 manufacturers made nearly \$9 million in payments to 14 outside groups between 2012 and
13 2017, and that physicians affiliated with those groups have been paid more than \$1.6 million
14 since 2013.²⁹ The Report further noted: “Payments from Purdue totaling \$4,153,554.33 account
15 for roughly half of the \$9 million in funding to groups.”³⁰ “Primarily due to large payments to
16 the National Pain Foundation (now known as the Global Pain Initiative) and the U.S. Pain
17 Foundation, Insys had the second-highest contribution total from 2012 to 2017, with
18
19

20 ²⁹ U.S. Senate Homeland Sec. & Governmental Affairs Committee, *Fueling an Epidemic: Exposing the Financial*
21 *Ties Between Opioid Manufacturers and Third Party Advocacy Groups*, (Feb. 12, 2018) at 1, available at
22 [https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf)
23 [Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf)
24 [Advocacy%20Groups.pdf](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf), (last accessed Aug. 10, 2018). On July 24, 2018, the Committee released a press release
25 U.S. Senate Homeland Sec. & Governmental Affairs Committee, *McCaskill Amends Report After Finding Insys*
26 *Therapeutics Failed to Report \$100,000 in Contributions to Third Party Advocacy Group*,
27 [https://www.hsgac.senate.gov/media/minority-media/mccaskill-amends-report-after-finding-insys-therapeutics-](https://www.hsgac.senate.gov/media/minority-media/mccaskill-amends-report-after-finding-insys-therapeutics-failed-to-report-100000-in-contributions-to-third-party-advocacy-group)
[failed-to-report-100000-in-contributions-to-third-party-advocacy-group](https://www.hsgac.senate.gov/media/minority-media/mccaskill-amends-report-after-finding-insys-therapeutics-failed-to-report-100000-in-contributions-to-third-party-advocacy-group) (last visited Aug. 10, 2018). Fueling and
Epidemic, Supplement to February 2018 Report, available at
<https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic->

1 \$3,146,265 in payments.”³¹ During the investigation for the report, the Global Pain Initiative
2 described \$662,500 in contributions from Insys in 2013, 2015, 2016, and 2017—\$100,000
3 more than Insys reported. In July 2018, Insys confirmed this additional \$100,000 payment to
4 the Global Pain Foundation.³²

5
6 120. On information and belief, the Manufacturer Defendants exercised control
7 over programs and materials created by these groups by collaborating on, editing, and
8 approving their content, and by funding their dissemination. In doing so, the Manufacturer
9 Defendants made sure that the Front Groups would generate only the messages the
10 Manufacturer Defendants wanted to distribute. Despite this, the Front Groups held themselves
11 out as independent and serving the needs of their members—whether patients suffering from
12 pain or doctors treating those patients.

13
14 121. Defendants Cephalon, Endo, Janssen and Purdue, in particular, utilized
15 many Front Groups, including many of the same ones. Several of the most prominent are
16 described below, but there are many others, including the American Pain Society (APS),
17 American Geriatrics Society (AGS), the Federation of State Medical Boards (FSMB), American
18 Chronic Pain Association (ACPA), the Center for Practical Bioethics (CPB), the U.S. Pain
19 Foundation (USPF),³³ and the Pain & Policy Studies Group (PPSG).³⁴

20
21
22 [Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf](#), (last accessed Sept. 20, 2018).

23 ³⁰ *Id.*

24 ³¹ *Id.*

25 ³² *Id.*

26 ³³ The U.S. Pain Foundation lists “Platinum,” “Gold,” and “Basic” corporate members—including Manufacturer
27 Defendants like Abbott, Teva, Janssen (through J&J), Endo, Purdue, and Mallinckrodt—without indicating the level
of donations required for each classification. They also list other Front Groups as members. U.S. Pain Foundation,
Transparency, <https://uspainfoundation.org/transparency/>, (last accessed Aug. 10, 2018).

1 122. The most prominent of the Manufacturer Defendants' Front Groups was the
2 APF, which, on information and belief, received more than \$10 million in funding from opioid
3 manufacturers (primarily from Endo and Purdue) from 2007 until it closed its doors in May
4 2012. APF issued education guides for patients, reporters, and policymakers that touted the
5 benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction.
6 APF also launched a campaign to promote opioids for returning veterans, which has
7 contributed to high rates of addiction and other adverse outcomes—including death—among
8 returning soldiers. APF also engaged in a significant multimedia campaign—through radio,
9 television, and the internet—to educate patients about their “right” to pain treatment, namely
10 opioids. All of the programs and materials were available nationally and were intended to reach
11 citizens of all 50 states.
12

13
14 123. APF held itself out as an independent patient advocacy organization. It often
15 engaged in grassroots lobbying against various legislative initiatives that might limit opioid
16 prescribing, and thus the profitability of its sponsors. Upon information and belief, APF was
17 often called upon to provide “patient representatives” for the Manufacturer Defendants'
18 promotional activities, including for Purdue's Partners Against Pain and Janssen's Let's Talk
19 Pain.
20

21 124. However, APF functioned largely as an advocate for the interests of the
22 Manufacturer Defendants, not patients. Indeed, upon information and belief, as early as 2001,
23

24 ³⁴ See generally, e.g., Letter from Sen. Ron Wyden, U.S. Senate Comm. on Finance, to Sec. Thomas E. Price, U.S.
25 Dep't of Health and Human Servs., (May 5, 2015), *available at*
26 <https://www.finance.senate.gov/imo/media/doc/050517%20Senator%20Wyden%20to%20Secretary%20Price%20re%20FDA%20Opioid%20Prescriber%20Working%20Group.pdf>, (last accessed Aug. 10, 2018).
27

1 Purdue told APF that the basis of a grant was Purdue's desire to "strategically align its
2 investments in nonprofit organizations that share [its] business interests."

3 125. Organizations, including the U.S. Senate Finance Committee, began to
4 investigate APF in 2012 to determine the links, financial and otherwise, between the organization
5 and the opioid industry.³⁵ The investigation revealed that APF received 90 percent of its funding
6 from the drug and medical-device industry, and "its guides for patients, journalists and policymakers
7 had played down the risks associated with opioid painkillers while exaggerating the benefits from
8 the drugs." Within days of the beginning of the Senate Finance Committee's investigation, APF
9 dissolved "due to irreparable economic circumstances."
10

11 126. Another front group for the Manufacturer Defendants was the AAPM. With the
12 assistance, prompting, involvement, and funding of the Manufacturer Defendants, the AAPM issued
13 purported treatment guidelines, and sponsored and hosted medical education programs essential to
14 the Manufacturer Defendants' deceptive marketing of chronic opioid therapy.
15

16 127. AAPM received substantial funding from opioid manufacturers. For
17 example, AAPM maintained a corporate relations council, whose members paid \$25,000 per
18 year (on top of other funding) to participate. The benefits included allowing members to
19 present educational programs at off-site dinner symposia in connection with AAPM's marquee
20 event, its annual meeting held in Palm Springs, California, or other resort locations. AAPM
21 describes the annual event as an "exclusive venue" for offering education programs to doctors.
22 Membership in the corporate relations council also allows drug company executives and
23
24

25 ³⁵ Charles Ornstein & Tracy Weber, *Senate panel investigates drug companies ties to pain groups*, The Washington
26 Post, May 8, 2012, available at <https://www.washingtonpost.com/national/health-science/senate-panel->
27

1 marketing staff to meet with AAPM executive committee members in small settings.
2 Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive
3 programs to doctors who attended this annual event. Defendant Teva is a current council
4 member.³⁶

5
6 128. Upon information and belief, AAPM is viewed internally by Endo as
7 “industry friendly,” with Endo advisors and speakers among its active members. Endo attended
8 AAPM conferences, funded its CMEs, and distributed its publications. The conferences
9 sponsored by AAPM heavily emphasized sessions on opioids—37 out of roughly 40 at one
10 conference alone. AAPM’s presidents have included top industry-supported KOLs Dr. Perry
11 Fine of the University of Utah and Dr. Lynn Webster. Dr. Webster was even elected president
12 of AAPM while under a DEA investigation.

13
14 129. The Manufacturer Defendants were able to influence AAPM through both
15 their significant and regular funding, and the leadership of pro-opioid KOLs within the
16 organization.

17
18 130. In 1996, AAPM and APS jointly issued a consensus statement, “The Use of
19 Opioids for the Treatment of Chronic Pain,” which endorsed opioids to treat chronic pain and
20 claimed that the risk of a patients’ addiction to opioids was low. Dr. Haddox, who co-authored
21 the AAPM/APS statement, was a paid speaker for Purdue at the time. Dr. Portenoy was the
22 sole consultant. The consensus statement remained on AAPM’s website until 2011, and, upon
23

24 [investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIOA2X4qBU_story.html](https://www.aapm.org/investigates-drug-companies-ties-to-paid-groups/2012/05/08/gIOA2X4qBU_story.html) (last accessed August 10,
25 2018).

26 ³⁶ AAPM, Corporate Relations Council Profiles, [http://www.painmed.org/membercenter/corporate-relations-](http://www.painmed.org/membercenter/corporate-relations-council-profiles/)
27 [council-profiles/](http://www.painmed.org/membercenter/corporate-relations-council-profiles/) (last accessed July 31, 2018).

1 information and belief, was taken down from AAPM's website only after a doctor
2 complained.³⁷

3 131. AAPM and APS issued their own guidelines in 2009 ("AAPM/APS
4 Guidelines") and continued to recommend the use of opioids as "safe and effective" for
5 treating chronic pain, despite acknowledging limited evidence, and concluding that the risk of
6 addiction is manageable for patients regardless of past abuse histories.³⁸ The AAPM/APS
7 Guidelines have been relied upon by doctors, especially the general practitioners and family
8 doctors targeted by the Manufacturer Defendants.

9
10 132. At least 14 of the 21 panel members, who drafted the AAPM/APS
11 Guidelines, (including KOLs Dr. Portenoy and Dr. Fine), received support from Janssen,
12 Cephalon, Endo, and Purdue. One panel member, Dr. Joel Saper, Clinical Professor of
13 Neurology at Michigan State University and founder of the Michigan Headache &
14 Neurological Institute, resigned from the panel because of his concerns that the 2009
15 Guidelines were influenced by contributions that drug companies, including Manufacturer
16 Defendants, made to the sponsoring organizations and committee members.

17
18 133. These AAPM/APS Guidelines have been a particularly effective channel of
19 deception and have influenced not only treating physicians, but also the body of scientific
20 evidence on opioids. The AAPM/APS Guidelines have been cited hundreds of times in
21 academic and scientific literature, and were reprinted in the Journal of Pain. Further, the
22
23

24 ³⁷ *The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of*
25 *Pain Medicine and the American Pain Society*, 13 Clinical J. Pain 6 (1997).

26 ³⁸ Roger Chou, et al., *Clinical guidelines for the use of chronic opioid therapy in chronic noncancer pain*, 10 J. Pain
27 113 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4043401/>.

1 AAPM/APS Guidelines are referenced by third-party payors in determining whether they
2 should cover treatments for specific indications.

3 134. The Manufacturer Defendants widely referenced and promoted the 2009
4 Guidelines without disclosing the lack of evidence to support them or the Manufacturer
5 Defendants' financial support to members of the panel. Pharmaceutical sales representatives
6 employed by Endo, Actavis, and Purdue discussed the guidelines with doctors during
7 individual sales visits.
8

9 135. On information and belief, the Manufacturer Defendants combined their
10 efforts through the Pain Care Forum (PCF), which began in 2004 as an APF project. PCF is
11 comprised of representatives from opioid manufacturers (including Abbott, Allergan,
12 Cephalon, Endo, Insys, Janssen (through J&J), Purdue and Teva) and various Front Groups,
13 almost all of which received substantial funding from the Manufacturer Defendants. Among
14 other projects, PCF worked to ensure that an FDA-mandated education project on opioids was
15 not unacceptably negative and did not require mandatory participation by prescribers. PCF also
16 worked to address a lack of coordination among its members and developed cohesive industry
17 messaging. Further, PCF worked to "influence legislation concerning prescription pain
18 medications on both federal and state levels," with an average of six lobbyists in Alaska from
19 2006-2015.³⁹
20
21

22 136. According to the Global Pain Initiative, Insys provided \$50,000 in 2013 "to
23 the organization without restrictions to start operations, in 4-separate payments of \$12,500.00
24

25 ³⁹ Eugene Tauber, *Lobbyists hired by advocates for opioid manufacturers in every state*, The Morning Call,
26 Sept. 17, 2016, <http://www.mcall.com/news/local/data/mc-politics-of-pain-state-lobbyists-htmlstory.html> (last
27 accessed Aug. 10, 2018).

1 each.” In 2015, Insys reportedly provided three payments totaling \$350,000 to “launch a race
2 car program ‘Global Pain Initiative’ to reach public for feedback,” to “launch data discovery as
3 to pain in the U.S. and move that to pain abroad,” and to develop a “‘digital data’ collection
4 tool for ‘person centric’ data.”⁴⁰

5
6 137. On information and belief, through Front Groups and KOLs, the
7 Manufacturer Defendants wrote or influenced prescribing guidelines that reflected the
8 messaging the Manufacturer Defendants wanted to promote rather than scientific evidence.

9 138. Through these means, and likely others still concealed, the Manufacturer
10 Defendants collaborated to spread deceptive messages about the risks and benefits of long-term
11 opioid use.

12
13 2. The Manufacturer Defendants’ false and misleading statements understated
14 the dangers of opioid drugs

15 139. To falsely assure physicians and patients that opioids are safe, the
16 Manufacturer Defendants deceptively trivialized and failed to disclose the risks of long-term
17 opioid use, particularly the risk of addiction, through a series of misrepresentations that have
18 been conclusively debunked by the FDA and CDC.

19 140. The Manufacturer Defendants’ misrepresentations reinforced each other and
20 created the dangerously misleading impressions that (a) starting patients on opioids was low-
21 risk because most patients would not become addicted, and because those who were at greatest
22 risk of addiction could be readily identified and managed; (b) patients who displayed signs of
23

24
25 ⁴⁰ Fueling and Epidemic, Supplement to February 2018 Report,
26 <https://www.hsgac.senate.gov/imo/media/doc/SUPPLEMENT-Fueling%20an%20Epidemic-Exposing%20the%20Financial%20Ties%20Between%20Opioid%20Manufacturers%20and%20Third%20Party%20Advocacy%20Groups.pdf>.

1 addiction probably were not addicted (and likely suffered from pseudoaddiction) and, in any
2 event, could easily be weaned from the drugs; (c) the use of higher opioid doses, which many
3 patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special
4 risks; and (d) abuse-deterrent opioids both prevent abuse and overdose and are inherently less
5 addictive.
6

7 141. Some examples of these false claims include:

- 8 a. Actavis's predecessor caused a patient education brochure, Managing
9 Chronic Back Pain, to be distributed beginning in 2003 that admitted that
10 opioid addiction is possible, but falsely claimed that it is "less likely if you
11 have never had an addiction problem." Based on Actavis's acquisition of its
12 predecessor's marketing materials along with the rights to Kadian, it appears
13 that Actavis continued to use this brochure in 2009 and beyond.
14
15 b. Cephalon and Purdue sponsored APF's Treatment Options: A Guide for
16 People Living with Pain (2007), which suggests that addiction is rare and
17 limited to extreme cases of unauthorized dose escalations, obtaining
18 duplicative prescriptions, or theft. This publication is available today.⁴¹
19
20 c. Endo sponsored a website, "PainKnowledge," which, upon information and
21 belief, claimed in 2009 that "[p]eople who take opioids as prescribed usually
22 do not become addicted." Upon information and belief, another Endo
23 website, PainAction.com, stated, "Did you know? Most chronic pain
24

25 ⁴¹ APF, *Treatment Options: A Guide for People Living with Pain* (2007), available at
26 <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last accessed Aug. 10, 2018).
27

1 patients do not become addicted to the opioid medications that are
2 prescribed for them.” Endo also distributed an “Informed Consent”
3 document on PainAction.com that misleadingly suggested that only people
4 who “have problems with substance abuse and addiction” are likely to
5 become addicted to opioid medications.
6

7 d. Upon information and belief, Endo distributed a pamphlet with the Endo
8 logo entitled *Living with Someone with Chronic Pain*, which stated, “[m]ost
9 health care providers who treat people with pain agree that most people do
10 not develop an addiction problem.”
11

12 e. Janssen reviewed and distributed a patient education guide entitled *Finding*
13 *Relief: Pain Management for Older Adults* (2009), which described as
14 “myth” the claim that opioids are addictive, and asserted as fact that
15 “[m]any studies show that opioids are rarely addictive when used properly
16 for the management of chronic pain.”
17

18 f. Janssen continues to maintain a website, *prescriberesponsibly.com* (last
19 modified July 2, 2015) which claims that concerns about opioid addiction
20 are “overestimated.”⁴²
21

22 g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain &*
23 *Its Management*, which claims that less than 1% of children prescribed
24 opioids will become addicted and that pain is undertreated due to
25

26 ⁴² Available at <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last accessed Aug. 10,
27 2018).

1 “misconceptions about opioid addiction[.]” This publication is still available
2 online.⁴³

3 142. Consistent with the Manufacturer Defendants’ published marketing materials,
4 upon information and belief, detailers for the Manufacturer Defendants in Alaska and elsewhere
5 have 1) minimized or omitted (and continue to minimize or omit) any discussion with doctors or
6 their medical staff about the risk of addiction; 2) misrepresented the potential for abuse of opioids
7 with purportedly abuse-deterrent formulations; and 3) failed to correct the misrepresentations
8 noted above.
9

10 143. The Manufacturer Defendants engaged in this campaign of misinformation
11 in an intentional effort to deceive doctors and patients and thereby increase the use of their
12 opioid products.
13

14 144. The Manufacturer Defendants’ misrepresentations are contrary to
15 longstanding scientific evidence.

16 145. As noted in the 2016 CDC Guideline endorsed by the FDA, there is
17 “extensive evidence” of the “possible harms of opioids (including opioid use disorder [an
18 alternative term for opioid addiction]).”⁴⁴ The Guideline points out that “[o]pioid pain
19 medication use presents serious risks, including . . . opioid use disorder”⁴⁵ and that “continuing
20 opioid therapy for [three] 3 months substantially increases risk for opioid use disorder.”⁴⁶
21

22 146. The FDA further exposed the falsity of Defendants’ claims about the low
23

24 ⁴³ APF, *A Policymaker's Guide to Understanding Pain & Its Management*, at 6 (Oct. 2011), available at
25 <http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf> (last accessed Aug. 10, 2018).

⁴⁴ 2016 CDC Guideline, *supra* note 16, at 15.

⁴⁵ *Id.* at 2.

⁴⁶ *Id.* at 25.

1 risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for
2 IR opioids in 2016. In its announcements, the FDA found that “most opioid drugs have ‘high
3 potential for abuse’” and that opioids “are associated with a substantial risk of misuse, abuse,
4 NOWS [neonatal opioid withdrawal syndrome], addiction, overdose and death.”⁴⁷ According
5 to the FDA, because of the “known serious risks” associated with long-term opioid use,
6 including “risks of addiction, abuse, and misuse, even at recommended doses, and because of
7 the greater risks of overdose and death,” opioids should be used only “in patients for whom
8 alternative treatment options” like non-opioid drugs have failed.⁴⁸ The FDA further
9 acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction “can
10 occur in patients appropriately prescribed [opioids].”

13 147. The Manufacturer Defendants have been, and are, aware that their
14 misrepresentations about opioids are false.

15 148. The NY AG, in a 2016 settlement agreement with Endo, found that opioid
16 “use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with
17 up to 40% of chronic pain patients treated in specialty and primary care outpatient centers
18 meeting the clinical criteria for an opioid use disorder.”⁴⁹ Endo had claimed on its
19

20 ⁴⁷ Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S.
21 Dep’t of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid
22 Prescribing at 3 (Sept. 10, 2013), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2012-P-0818-0793&attachmentNumber=1&contentType=pdf> (last accessed Aug. 10, 2018); Letter from Janet
23 Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food & Drug Admin., U.S. Dep’t of Health
24 and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan & Becker, LLP at 7 (Mar. 22,
2016), available at <https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf> (last accessed Aug. 10, 2018) (emphasis added).

25 ⁴⁸ *Id.* at page 8 for both documents, respectively (emphasis added).

26 ⁴⁹ Assurance of Discontinuance, *In re Endo Health Solutions Inc. and Endo Pharm. Inc.* (Assurance No. 15-228), at
27 13, available at https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf (last accessed August 10, 2018).

1 www.opana.com website that “[m]ost healthcare providers who treat patients with pain agree
2 that patients treated with prolonged opioid medicines usually do not become addicted,”⁵⁰ but the
3 NY AG found that Endo had no evidence for that statement. Consistent with this, Endo agreed
4 not to “make statements that . . . opioids generally are non-addictive” or “that most patients who
5 take opioids do not become addicted” in New York.⁵¹

6
7 149. The Manufacturer Defendants falsely instructed doctors and patients that the
8 signs of addiction are actually signs of undertreated pain and should be treated by prescribing
9 more opioids. The Manufacturer Defendants called this phenomenon “pseudoaddiction”—a
10 term coined by Dr. J. David Haddox, who later became Vice President of Health Policy at
11 Purdue, and popularized by Dr. Portenoy—and falsely claimed that pseudoaddiction is
12 substantiated by scientific evidence. Some illustrative examples of these deceptive claims are
13 described below:

- 14
15 a. Cephalon and Purdue sponsored Responsible Opioid Prescribing (2007),
16 which taught that behaviors such as “requesting drugs by name”,
17 “demanding or manipulative behavior,” seeing more than one doctor to
18 obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than
19 true addiction. The 2012 edition of *Responsible Opioid Prescribing* remains
20 for sale online.⁵²
21
22 b. On information and belief, Janssen sponsored, funded, and edited the Let’s
23 Talk Pain website, which in 2009 stated: “pseudoaddiction . . . refers to
24

25 ⁵⁰ *Id.* at 6.

26 ⁵¹ *Id.* at 15.

27 ⁵² See Scott M. Fishman, M.D., *Responsible Opioid Prescribing: A Clinician’s Guide* (2d ed. 2012).

1 patient behaviors that may occur when pain is *under-treated*

2 Pseudoaddiction is different from true addiction because such behaviors can
3 be resolved with effective pain management.”

4
5 c. Endo sponsored a National Initiative on Pain Control (NIPC) CME program
6 in 2009 entitled “Chronic Opioid Therapy: Understanding Risk While
7 Maximizing Analgesia,” which, upon information and belief, promoted
8 pseudoaddiction by teaching that a patient’s aberrant behavior was the result
9 of untreated pain. Endo appears to have substantially controlled NIPC by
10 funding NIPC projects; developing, specifying, and reviewing content; and
11 distributing NIPC materials.

12
13 d. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing*
14 *Abuse*, which, upon information and belief, described pseudoaddiction as a
15 concept that “emerged in the literature” to describe the inaccurate
16 interpretation of [drug- seeking behaviors] in patients who have pain that
17 has not been effectively treated.”

18
19 e. Upon information and belief, Purdue sponsored a CME program titled “Path
20 of the Patient, Managing Chronic Pain in Younger Adults at Risk for
21 Abuse”. In a role play, a chronic pain patient with a history of drug abuse
22 tells his doctor that he is taking twice as many hydrocodone pills as directed.
23 The narrator notes that because of pseudoaddiction, the doctor should not
24 assume the patient is addicted even if he persistently asks for a specific
25 drug, seems desperate, hoards medicine, or “overindulges in unapproved
26
27

1 escalating doses.” The doctor treats this patient by prescribing a high-dose,
2 long acting opioid.

3 150. Pseudoaddiction is fictional. The 2016 CDC Guideline rejects the concept of
4 pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if a
5 patient is not experiencing pain relief. To the contrary, the Guideline explains that “[p]atients
6 who do not experience clinically meaningful pain relief early in treatment . . . are unlikely to
7 experience pain relief with longer-term use,”⁵³ and that physicians should “reassess[] pain and
8 function within 1 month” in order to decide whether to “minimize risks of long-term opioid use
9 by discontinuing opioids” because the patient is “not receiving a clear benefit.”⁵⁴
10

11 151. In connection with its settlement with the NY AG, Endo was forced to admit
12 that the concept of pseudoaddiction was a sham. In finding that “[t]he ‘pseudoaddiction’
13 concept has never been empirically validated and in fact has been abandoned by some of its
14 proponents,” the NY AG, in its 2016 settlement with Endo, reported that despite the fact that
15 Endo trained its sales representatives to use the concept of pseudoaddiction, “Endo’s Vice
16 President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was
17 not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the
18 difficulty in distinguishing “between addiction and ‘pseudoaddiction.’”⁵⁵
19
20

21 152. The Manufacturer Defendants falsely instructed doctors and patients that
22 addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow
23 them to reliably identify and safely prescribe opioids to patients predisposed to addiction.
24

25 ⁵³ 2016 CDC Guideline, *supra* note 16, at 13.

26 ⁵⁴ *Id.* at 25.

27 ⁵⁵ Assurance of Discontinuance, *supra* note 49, at 7.

1 These misrepresentations were especially insidious because the Manufacturer Defendants
2 aimed them at general practitioners and family doctors who lack the time and expertise to
3 closely manage higher-risk patients on opioids. The Manufacturer Defendants'
4 misrepresentations made these doctors feel more comfortable prescribing opioids to their
5 patients, and patients more comfortable starting on opioid therapy for chronic pain. Some
6 illustrative examples of these deceptive claims are described below:
7

- 8 a. On information and belief, Endo paid for a 2007 supplement in the Journal
9 of Family Practice written by a doctor who became a member of Endo's
10 speakers bureau in 2010. The supplement, entitled "Pain Management
11 Dilemmas in Primary Care: Use of Opioids", emphasized the effectiveness
12 of screening tools, claiming that patients at high risk of addiction could
13 safely receive chronic opioid therapy using a "maximally structured
14 approach" involving toxicology screens and pill counts.
15
- 16 b. On information and belief, Purdue sponsored a November 2011 webinar,
17 *Managing Patient's Opioid Use: Balancing the Need and Risk*, which
18 claimed that screening tools, urine tests, and patient agreements prevent
19 "overuse of prescriptions" and "overdose deaths."
20
- 21 c. On information and belief, as recently as 2015, Purdue has represented in
22 scientific conferences that "bad apple" patients—and not opioids—are the
23 source of the addiction crisis and that once those "bad apples" are identified,
24 doctors can safely prescribe opioids without causing addiction.
25
- 26 d. On information and belief, detailers for the Manufacturer Defendants have
27

1 touted and continue to tout to doctors in Alaska the reliability and
2 effectiveness of screening or monitoring patients as a tool for managing
3 opioid abuse and addiction.

4 153. Once again, the 2016 CDC Guideline confirms that these statements were
5 false, misleading, and unsupported at the time they were made by the Manufacturer
6 Defendants. The Guideline notes that there are no studies assessing the effectiveness of risk
7 mitigation strategies—such as screening tools, patient contracts, urine drug testing, or pill
8 counts widely believed by doctors to detect and deter abuse—”for improving outcomes related
9 to overdose, addiction, abuse, or misuse.”⁵⁶ As a result, the Guideline recognizes that available
10 risk screening tools “show insufficient accuracy for classification of patients as at low or high
11 risk for [opioid] abuse or misuse” and counsels that doctors “should not overestimate the
12 ability of these tools to rule out risks from long-term opioid therapy.”⁵⁷

13 154. To underplay the risk and impact of addiction and make doctors feel more
14 comfortable starting patients on opioids, the Manufacturer Defendants falsely claimed that
15 opioid dependence can easily be addressed by tapering and that opioid withdrawal is not a
16 problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

17 155. For example, on information and belief, a 2011 non-credit educational
18 program sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that
19 withdrawal symptoms can be avoided by tapering a patient’s opioid dose by 10%-20% for 10
20 days.

21 156. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain &*
22

1 *Its Management*, which claimed that “[s]ymptoms of physical dependence can often be
2 ameliorated by gradually decreasing the dose of medication during discontinuation” without
3 mentioning any hardships that might occur.⁵⁸

4
5 157. The Manufacturer Defendants deceptively minimized the significant
6 symptoms of opioid withdrawal, which, as explained in the 2016 CDC Guideline, include drug
7 craving, anxiety, insomnia, abdominal pain, vomiting, diarrhea, tremor, and tachycardia (rapid
8 heartbeat). The Marketing Defendants also grossly understated the difficulty of tapering,
9 particularly after long-term opioid use.

10
11 158. Contrary to the Manufacturer Defendants’ representations, the 2016 CDC
12 Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed
13 should be “limit[ed]” to “minimize the need to taper opioids to prevent distressing or
14 unpleasant withdrawal symptoms,” because “physical dependence on opioids is an expected
15 physiologic response in patients exposed to opioids for more than a few days.”⁵⁹ The Guideline
16 further states that “more than a few days of exposure to opioids significantly increases
17 hazards” and “each day of unnecessary opioid use increases likelihood of physical dependence
18 without adding benefit.”⁶⁰

19
20 159. The Manufacturer Defendants falsely claimed that doctors and patients
21 could increase opioid dosages indefinitely without added risk and failed to disclose the greater
22 risks to patients at higher dosages. The ability to escalate dosages was critical to the
23

24 ⁵⁶ 2016 CDC Guideline, *supra* note 16, at 11.

25 ⁵⁷ *Id.* at 28 (emphasis added).

26 ⁵⁸ APF, *Policymaker's Guide*, *supra* note 43 at 32.

27 ⁵⁹ 2016 CDC Guideline, *supra* note 16, at 24.

⁶⁰ *Id.*

1 Manufacturer Defendants' efforts to market opioids for long-term use to treat chronic pain
2 because, absent this misrepresentation, doctors would have abandoned treatment when patients
3 built up tolerance and lower dosages did not provide pain relief. Some illustrative examples of
4 these deceptive claims are described below:

- 5 a. On information and belief, Actavis's predecessor created a patient brochure
6 for Kadian in 2007 that stated, "Over time, your body may become tolerant
7 of your current dose. You may require a dose adjustment to get the right
8 amount of pain relief. This is not addiction."
- 9 b. Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for*
10 *People Living with Pain* (2007), which claims that some patients "need" a
11 larger dose of an opioid, regardless of the dose currently prescribed. The
12 guide stated that opioids have "no ceiling dose" and are therefore the most
13 appropriate treatment for severe pain. This guide is still available online.⁶¹
- 14 c. Endo sponsored a website, "PainKnowledge," which, upon information and
15 belief, claimed in 2009 that opioid dosages may be increased until "you are
16 on the right dose of medication for your pain."
- 17 d. Endo distributed a pamphlet edited by a KOL entitled *Understanding Your*
18 *Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-
19 0120). In Q&A format, it asked "If I take the opioid now, will it work later
20 when I really need it?" The response is, "The dose can be increased. . . . You
21
22
23
24

25 ⁶¹ APF, *Treatment Options*, *supra* note 41, at 12.

won't 'run out' of pain relief.”⁶²

- e. Janssen, on information and belief, sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which its sales force distributed. This guide listed dosage limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased opioid dosages.
- f. On information and belief, Purdue’s *In the Face of Pain* website promoted the notion that if a patient’s doctor does not prescribe what, in the patient’s view, is a sufficient dosage of opioids, he or she should find another doctor who will.
- g. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which taught that dosage escalations are “sometimes necessary,” even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online.⁶³
- h. On information and belief, in 2007, Purdue sponsored a CME entitled “Overview of Management Options” that was available until at least 2012. The CME was edited by a KOL and taught that nonsteroidal anti-inflammatories (or NSAIDs) and other drugs, but not opioids, are unsafe at high dosages.
- i. Seeking to overturn the criminal conviction of a doctor for illegally

⁶² Margo McCaffery & Chris Pasero, Endo Pharm., *Understanding Your Pain: Taking Oral Opioid Analgesics* (Russell K. Portenoy, M.D., ed., 2004).

⁶³ APF, *Policymaker’s Guide*, *supra* note 43, at 32.

1 prescribing opioids, the Front Group APF and others argued to the United
2 States Court of Appeals for the Fourth Circuit that “there is no ‘ceiling
3 dose’” for opioids.⁶⁴

4 j. On information and belief, Purdue’s detailers have told doctors in Alaska
5 that they should increase the dose of OxyContin, rather than the frequency
6 of use, to address early failure.

7
8 160. These claims conflict with the scientific evidence, as confirmed by the FDA
9 and CDC. As the CDC explains in its 2016 Guideline, the “[b]enefits of high-dose opioids for
10 chronic pain are not established” while the “risks for serious harms related to opioid therapy
11 increase at higher opioid dosage.” More specifically, the CDC explains, “there is now an
12 established body of scientific evidence showing that overdose risk is increased at higher opioid
13 dosages.” The CDC also states that there are “increased risks for opioid use disorder,
14 respiratory depression, and death at higher dosages.”⁶⁵

15
16 161. The Manufacturer Defendants’ deceptive marketing of the so-called abuse-
17 deterrent properties of some of their opioids has created false impressions that these opioids
18 can prevent and curb addiction and abuse.

19
20 162. These abuse deterrent formulations (AD opioids) purportedly are harder to
21 crush, chew, or grind; become gelatinous when combined with a liquid, making them harder to
22 inject; or contain a counteragent such as naloxone that is activated if the tablets are tampered
23

24 ⁶⁴ Brief of the American Pain Foundation (APF), the National Pain Foundation, and the National Foundation for the
25 Treatment of Pain in Support of Appellant and Reversal of the Conviction, *United States v. Hurowitz*, No. 05-4474,
26 at 9 (4th Cir. Sept. 8, 2005).

27 ⁶⁵ 2016 CDC Guideline, *supra* note 16, at 22-24.

1 with. Despite this, AD opioids can be defeated—often quickly and easily—by those
2 determined to do so. The 2016 CDC Guideline states that “[n]o studies” support the notion that
3 “abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing
4 abuse,”⁶⁶ noting that the technologies—even when they work—do not prevent opioid abuse
5 through oral intake, the most common route of opioid abuse, and can still be abused by non-
6 oral routes. Moreover, they do not reduce the rate of misuse and abuse by patients who become
7 addicted after using opioids long-term as prescribed or who escalate their use by taking more
8 pills or higher doses. Tom Frieden, the Director of the CDC under President Obama, has
9 further reported that his staff could not find “any evidence showing the updated opioids
10 [ADFs] actually reduce rates of addiction, overdoses, or deaths.”⁶⁷
11

12
13 163. Despite this lack of evidence, the Manufacturer Defendants have made and
14 continue to make misleading claims about the ability of their so-called abuse-deterrent opioid
15 formulations to prevent or reduce abuse and addiction and the safety of these formulations.

16 164. For example, Endo has marketed Opana ER⁶⁸ as tamper- or crush-resistant
17 and less prone to misuse and abuse even though: (1) on information and belief, the FDA
18 warned in a 2013 letter that there was no evidence that Opana ER would provide a reduction in
19 oral, intranasal or intravenous abuse; and (2) Endo’s own studies, which it failed to disclose,
20 showed that Opana ER could still be ground and chewed. Nonetheless, Endo’s advertisements
21
22

23 ⁶⁶ 2016 CDC Guideline, *supra* note 16, at 22.

24 ⁶⁷ Perrone, et al., *supra* note 15.

25 ⁶⁸ Because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and a serious
26 blood disease, in May 2017, an FDA advisory committee recommended that Opana ER be withdrawn from the
27 market. The FDA adopted this recommendation on June 8, 2017 and requested that Endo withdraw Opana ER from
the market. Press Release, “FDA requests removal of Opana ER for risks related to abuse,” June 8, 2017, *available*
at <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm> (last accessed Feb. 27,
2018).

1 for Opana ER falsely claimed that it was designed to be crush resistant, in a way that suggested
2 it was more difficult to abuse, and on information and belief, detailers for Endo have informed
3 doctors that Opana ER is harder to abuse.

4
5 165. In its 2016 settlement with the NY AG, Endo agreed not to make statements
6 in New York that Opana ER was “designed to be, or is crush resistant.” The NY AG found
7 those statements false and misleading because there was no difference in the ability to extract
8 the narcotic from Opana ER. The NY AG also found that Endo failed to disclose its own
9 knowledge of the crushability of redesigned Opana ER in its marketing to formulary
10 committees and pharmacy benefit managers.

11
12 166. Likewise, Purdue has engaged and continues to engage in deceptive
13 marketing of its AD opioids, i.e., reformulated OxyContin and Hysingla. Before April 2013,
14 Purdue did not market its opioids based on their abuse deterrent properties. However,
15 beginning in 2013, and continuing today, detailers from Purdue regularly use the so-called
16 abuse deterrent properties of Purdue’s opioid products as a primary selling point to
17 differentiate those products from their competitors. Specifically, on information and belief,
18 these detailers: (1) falsely claim that Purdue’s AD opioids prevent tampering and cannot be
19 crushed or snorted; (2) falsely claim that Purdue’s AD opioids prevent or reduce opioid misuse,
20 abuse, and diversion, are less likely to yield a euphoric high, and are disfavored by opioid
21 abusers; (3) falsely claim Purdue’s AD opioids are “safer” than other opioids; and (4) fail to
22 disclose that Purdue’s AD opioids do not impact oral abuse or misuse and that its abuse
23 deterrent properties can be defeated.

24
25
26 167. These statements and omissions by Purdue are false and misleading. Purdue
27

1 knew and should have known that reformulated OxyContin is not better at tamper resistance
2 than the original OxyContin and is still regularly tampered with and abused. A 2015 study also
3 shows that many opioid addicts are abusing Purdue's AD opioids through oral intake or by
4 defeating the abuse deterrent mechanism. Indeed, one-third of the patients in the study defeated
5 the abuse deterrent mechanism and were able to continue inhaling or injecting the drug. To the
6 extent that the abuse of Purdue's AD opioids was reduced, those addicts simply shifted to other
7 drugs such as heroin.⁶⁹ Despite this, J. David Haddox, the Vice President of Health Policy for
8 Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's AD opioids are
9 being abused in large numbers.⁷⁰

12 168. The development, marketing, and sale of AD opioids is a continuation of the
13 Manufacturer Defendants' strategy to use misinformation to drive profit. The Manufacturer
14 Defendants' claims that AD opioids are safe falsely assuage doctors' concerns about the toll
15 caused by the explosion in opioid abuse, causing doctors to prescribe more AD opioids, which
16 are far more expensive than other opioid products even though they provide little or no
17 additional benefit.

19 3. The Manufacturer Defendants' false and misleading statements overstated
20 the benefits of chronic opioid therapy

21 169. To convince doctors and patients that opioids should be used to treat chronic
22 pain, the Manufacturer Defendants also had to persuade them that there was a significant

23 ⁶⁹ Cicero, Theodore J., and Matthew S. Ellis, *Abuse-deterrent formulations and the Prescription Opioid Abuse*
24 *Epidemic in the United States: Lessons Learned From Oxycontin* (2015) 72(5) JAMA PSYCHIATRY 424-430.

25 ⁷⁰ See Harrison Jacobs, *There is a big problem with the government's plan to stop the drug-overdose epidemic*,
26 Business Insider, Mar. 14, 2016, available at <http://www.businessinsider.com/robert-califf-abuse-deterrent-drugs-have-a-big-flaw-2016-3> (last accessed Feb. 27, 2018).

1 upside to long-term opioid use.

2 170. The 2016 CDC Guideline makes clear that there is “insufficient evidence to
3 determine long-term benefits of opioid therapy for chronic pain.”⁷¹ In fact, the CDC found that
4 “[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for
5 chronic pain with outcomes examined at least 1 year later (with most placebo-controlled
6 randomized trials ≤ 6 weeks in duration)”⁷² and that other treatments were more or equally
7 beneficial and less harmful than long-term opioid use.
8

9 171. The FDA, too, has recognized the lack of evidence to support long-term
10 opioid use. In 2013, the FDA stated that it was “not aware of adequate and well-controlled
11 studies of opioid use longer than 12 weeks.”⁷³
12

13 172. Despite this, the Manufacturer Defendants falsely and misleadingly touted
14 the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits
15 were supported by scientific evidence. Not only have the Manufacturer Defendants failed to
16 correct these false and misleading claims, they continue to make them today.
17

18 173. For example, the Manufacturer Defendants falsely claimed that long-term
19 opioid use improved patients’ function and quality of life. Some illustrative examples of these
20 deceptive claims are described below:

- 21 a. On information and belief, Actavis distributed an advertisement that claimed
22 that the use of Kadian to treat chronic pain would allow patients to return to
23 work, relieve “stress on your body and your mental health,” and help
24

25 ⁷¹ 2016 CDC Guideline, *supra* note 16, at 19.

26 ⁷² *Id.* at 15.

27 ⁷³ Letter from Janet Woodcock to Andrew Koldny, *supra* note 47, at 9.

1 patients enjoy their lives.

2 b. Endo distributed advertisements that claimed that the use of Opana ER for
3 chronic pain would allow patients to perform demanding tasks like
4 construction work or work as a chef and portrayed seemingly healthy,
5 unimpaired subjects.
6

7 c. On information and belief, Janssen sponsored and edited a patient education
8 guide entitled *Finding Relief: Pain Management for Older Adults* (2009),
9 which states as “a fact” that “opioids may make it easier for people to live
10 normally.” The guide lists expected functional improvements from opioid
11 use, including sleeping through the night, returning to work, recreation, sex,
12 walking, and climbing stairs and states that “[u]sed properly, opioid
13 medications can make it possible for people with chronic pain to ‘return to
14 normal.’”
15

16 d. *Responsible Opioid Prescribing* (2007), sponsored and distributed by Endo
17 and Purdue, taught that relief of pain by opioids, by itself, improved
18 patients’ function. The book remains for sale online.
19

20 e. APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored
21 by Cephalon and Purdue, counseled patients that opioids “give [pain
22 patients] a quality of life we deserve.” This publication is still available
23 online.⁷⁴
24

25 f. On information and belief, Endo’s NIPC website *painknowledge.com*
26
27

1 claimed that with opioids, “your level of function should improve; you may
2 find you are now able to participate in activities of daily living, such as work
3 and hobbies, that you were not able to enjoy when your pain was worse.”
4 Elsewhere, the website touted improved quality of life (as well as “improved
5 function”) as benefits of opioid therapy.
6

7 g. On information and belief, Janssen sponsored, funded, and edited a website,
8 *Let’s Talk Pain*, in 2009, which featured an interview edited by Janssen
9 claiming that opioids allowed a patient to “continue to function.”
10

11 h. Purdue sponsored the development and distribution of APF’s *A*
12 *Policymaker’s Guide to Understanding Pain & Its Management*, which
13 claimed that “multiple clinical studies” have shown that opioids are
14 effective in improving daily function, psychological health, and health-
15 related quality of life for chronic pain patients.⁷⁵ The Policymaker’s Guide
16 is still available online today.
17

18 i. In a 2015 video on Forbes.com discussing the introduction of Hysingla ER,
19 Purdue’s Vice President of Health Policy, J. David Haddox, talked about the
20 importance of opioids, including Purdue’s opioids, to chronic pain patients’
21 “quality of life,” and complained that CDC statistics do not take into
22 account that patients could be driven to suicide without pain relief.⁷⁶
23

24 ⁷⁴ APF, *Treatment Options*, *supra* note 41, at 15.

25 ⁷⁵ APF, *Policymaker’s Guide*, *supra* note 43, at 29.

26 ⁷⁶ Matthew Harper, *Why Supposedly Abuse-Proof Pills Won’t Stop Opioid Overdose Deaths*, Forbes (Apr. 17,
27 2015), available at <https://www.forbes.com/sites/matthewherper/2015/04/17/why-supposedly-abuse-proof-pills-pill-wont-stop-opioid-overdose-deaths/#6a4e41f06ce1> (last accessed Aug. 13, 2018).

1 174. The above claims find no support in the scientific literature. The 2016 CDC
2 Guideline approved by the FDA concluded “there is no good evidence that opioids improve
3 pain or function with long-term use, and . . . complete relief of pain is unlikely.”⁷⁷ The CDC
4 reinforced this conclusion throughout its 2016 Guideline:

- 5
- 6 a. “No evidence shows a long-term benefit of opioids in pain and function
7 versus no opioids for chronic pain with outcomes examined at least 1 year
8 later . . .”⁷⁸
- 9 b. “Although opioids can reduce pain during short-term use, the clinical
10 evidence review found insufficient evidence to determine whether pain
11 relief is sustained and whether function or quality of life improves with
12 long-term opioid therapy.”⁷⁹
- 13 c. “[E]vidence is limited or insufficient for improved pain or function with
14 long-term use of opioids for several chronic pain conditions for which
15 opioids are commonly prescribed, such as low back pain, headache, and
16 fibromyalgia.”⁸⁰
- 17
- 18

19 175. The CDC also noted that the risks of addiction and death “can cause distress
20 and inability to fulfill major role obligations.”⁸¹ As a matter of common sense (and medical
21 evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not
22 improve their function and quality of life.

23

24 ⁷⁷ 2016 CDC Guideline, *supra* note 16, at 20. (Emphasis added).

25 ⁷⁸ *Id.* at 15.

26 ⁷⁹ *Id.* at 18.

27 ⁸⁰ *Id.* at 18-19.

⁸¹ *Id.* at 20.

176. The 2016 CDC Guideline was not the first time a federal agency repudiated the Manufacturer Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life."⁸² Upon information and belief, in 2008, the FDA sent a warning letter to an opioid manufacturer, making it publicly clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."⁸³

177. The Manufacturer Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like over-the-counter NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. For example, the Manufacturer Defendants frequently pointed to the lack of a ceiling dosage for opioids in contrast to NSAIDs. The Manufacturer Defendants deceptively described the risks from NSAIDs while failing to disclose the risks from opioids, and they overstated the number of deaths from NSAIDs. Once again, these misrepresentations by the Manufacturer Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific

⁸² Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth LLC, Feb. 18, 2010, at 5, *available at*

<https://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf> (last accessed Aug. 10, 2018).

⁸³ Letter from Thomas Abrams, Dir., FDA Div. of Mktg., Adver., & Commc'ns, to Brian A. Markison, Chairman, President and Chief Executive Officer, King Pharmaceuticals, Inc. (March 24, 2008).

1 evidence. For example, the 2016 CDC Guideline states that NSAIDs, not opioids, should be the
2 first-line treatment for chronic pain, particularly arthritis and lower back pain.

3 178. For example, Purdue, with assistance from Abbott between 1996 and 2002,
4 misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous
5 hours of pain relief with one dose. OxyContin does not last for 12 hours—a fact that Purdue
6 has known at all times relevant to this action.⁸⁴ Upon information and belief, Purdue’s own
7 research shows that OxyContin wears off in under six hours in one quarter of patients and in
8 under 10 hours in more than half. This is because OxyContin tablets release approximately
9 40% of their active medicine immediately, after which release tapers. This triggers a powerful
10 initial response, but provides little or no pain relief at the end of the dosing period, when less
11 medicine is released. This phenomenon is known as “end of dose” failure, and the FDA found
12 in 2008 that a “substantial proportion” of chronic pain patients taking OxyContin experience it.
13 This not only renders Purdue’s promise of 12 hours of relief false and deceptive, it also makes
14 OxyContin more dangerous because the declining pain relief patients experience toward the
15 end of each dosing period drives them to take more OxyContin before the next dosing period
16 begins, quickly increasing the amount of drug they are taking and spurring growing
17 dependence.
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21 179. Cephalon deceptively marketed its opioids Actiq and Fentora for chronic
22 pain even though the FDA has expressly limited their use to the treatment of cancer pain in
23 opioid tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR
24 opioids. Neither is approved for, or has been shown to be safe or effective for, chronic pain.
25
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27

1 Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer
2 pain, and refused to approve Fentora for the treatment of chronic pain because of the potential
3 harm.

4
5 180. Despite this, on information and belief, Cephalon conducted and continues
6 to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other
7 non-cancer conditions for which it was not approved, appropriate or safe.⁸⁵ As part of this
8 campaign, Cephalon used CMEs, speaker programs, KOLs, journal supplements, and detailing
9 by its sales representatives to give doctors the false impression that Actiq and Fentora are safe
10 and effective for treating non-cancer pain. For example:

- 11
12 a. Cephalon paid to have a CME it sponsored, *Opioid-Based Management of*
13 *Persistent and Breakthrough Pain*, published in a supplement of Pain
14 Medicine News in 2009. The CME instructed doctors that “[c]linically,
15 broad classification of pain syndromes as either cancer- or non-cancer-
16 related has limited utility” and recommended Actiq and Fentora for patients
17 with chronic pain.
18
19 b. Upon information and belief, Cephalon’s sales representatives set up
20 hundreds of speaker programs for doctors, including many non-oncologists,
21 which promoted Actiq and Fentora for the treatment of non-cancer pain.
22
23 c. In December 2011, Cephalon widely disseminated a journal supplement
24 entitled “Special Report: An Integrated Risk Evaluation and Mitigation

25 ⁸⁴ See Ryan, et al., *supra* note 15.

26 ⁸⁵ See Press Release, U.S. Dep’t of Justice, *Biopharmaceutical Company, Cephalon, to Pay \$425 million & Enter*
27 *Plea To Resolve Allegations of Off-Label Marketing* (Sept. 29, 2008),

1 Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal
2 Fentanyl Citrate (ACTIQ)” to Anesthesiology News, Clinical Oncology
3 News, and Pain Medicine News—three publications that are sent to
4 thousands of anesthesiologists and other medical professionals. The Special
5 Report openly promotes Fentora for “multiple causes of pain”—and not just
6 cancer pain.
7

8 181. Cephalon’s deceptive marketing gave doctors and patients the false
9 impression that Actiq and Fentora were not only safe and effective for treating chronic pain,
10 but were also approved by the FDA for such uses.
11

12 182. Likewise, Insys aggressively and misleadingly promoted Subsys—that has
13 been approved by the FDA only for management of breakthrough pain in adult cancer
14 patients—as safe and appropriate for non-cancer pain such as neck and back pain, without
15 disclosing the lack of approval or evidence for such uses, and misrepresented the
16 appropriateness of Subsys for treatment of those conditions. Insys specifically targeted doctors
17 other than oncologists, including by paying them through its fraudulent speaker program
18 (discussed below), and training its sales force to encourage physicians to prescribe Subsys for
19 patients who were suffering from non-cancer pain.⁸⁶
20

21 4. The Manufacturer Defendants knew that their representations were false and
22 misleading, and fraudulently concealed their conduct to avoid detection
23

24 <https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html> (last accessed Aug. 10, 2018).

25 ⁸⁶ Specific instances of this conduct are described in a complaint filed by the Department of Justice, intervening in
26 five lawsuits that accuse Insys of violating the False Claims Act and other federal laws in connection with the
27 marketing of Subsys. United States Complaint in Intervention, No. 2:13-cv-05861 (C.D. Cal. Apr. 13, 2018),
available at <https://www.justice.gov/opa/press-release/file/1063051/download>.

1 183. As alleged herein, the Manufacturer Defendants made and/or disseminated
2 deceptive statements regarding material facts and further concealed material facts, in the course
3 of manufacturing, marketing, and selling prescription opioids. The Manufacturer Defendants'
4 actions were intentional and/or unlawful. Such statements include, but are not limited to, those
5 set out above and alleged throughout this Complaint.
6

7 184. On information and belief, the Manufacturer Defendants coordinated their
8 messaging through national and regional sales and speaker trainings and coordinated
9 advertisements and marketing materials.
10

11 185. The Manufacturer Defendants, both individually and collectively, made,
12 promoted, and profited from their misrepresentations about the risks and benefits of opioids for
13 chronic pain even though they knew that their misrepresentations were false and misleading.
14

15 186. The history of opioids, as well as research and clinical experience over the
16 last 20 years, established that opioids were highly addictive and responsible for a long list of
17 very serious adverse outcomes. The Manufacturer Defendants had access to scientific studies,
18 detailed prescription data, and reports of adverse events, including reports of addiction,
19 hospitalization, and deaths—all of which made clear the harms from long-term opioid use and
20 that patients are suffering from addiction, overdoses, and death in alarming numbers. More
21 recently, the FDA and CDC have issued pronouncements based on the medical evidence that
22 conclusively expose the known falsity of the Manufacturer Defendants' misrepresentations.
23 Defendants Endo and Purdue have recently entered agreements in New York prohibiting them
24 from making some of the same misrepresentations described in this Complaint.
25

26 187. Moreover, at all times relevant to this Complaint, the Manufacturer
27

1 Defendants took steps to avoid detection of and to fraudulently conceal their deceptive
2 marketing and unlawful, unfair, and fraudulent conduct. For example, the Manufacturer
3 Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by
4 funding and working through third parties like Front Groups and KOLs. The Manufacturer
5 Defendants purposefully hid behind the assumed credibility of these individuals and
6 organizations and relied on them to vouch for the accuracy and integrity of the Manufacturer
7 Defendants' false and misleading statements about the risks and benefits of long-term opioid
8 use for chronic pain.
9

10 188. The Manufacturer Defendants also never disclosed their role in shaping,
11 editing, and approving the content of information and materials disseminated by these third
12 parties. The Manufacturer Defendants exerted considerable influence on these promotional and
13 "educational" materials in emails, correspondence, and meetings with KOLs, Front Groups,
14 and public relations companies that were not made public.
15

16 189. Finally, the Manufacturer Defendants manipulated their promotional
17 materials and the scientific literature to make it appear that these items were accurate, truthful,
18 and supported by objective evidence when they were not. The Manufacturer Defendants
19 distorted the meaning or import of studies they cited and offered them as evidence for
20 propositions the studies did not support. The Manufacturer Defendants invented
21 "pseudoaddiction" and promoted it to an unsuspecting medical community. The Manufacturer
22 Defendants provided the medical community with false and misleading information about
23 ineffectual strategies to avoid or control opioid addiction. The Manufacturer Defendants
24 recommended to the medical community that dosages be increased, without disclosing the
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27

1 risks.

2 190. The Manufacturer Defendants spent millions of dollars over a period of
3 years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising
4 the risks, and promoting sales. The lack of support for the Manufacturer Defendants' deceptive
5 messages was not apparent to medical professionals who relied upon them in making treatment
6 decisions.
7

8 191. Upon information and belief, the use of opioids by individuals served by the
9 Plaintiff who were addicted or who did not have a medically necessary purpose would not have
10 occurred without the activities of Manufacturer Defendants alleged in this Complaint.
11

12 5. Defendant Insys went beyond false and misleading marketing to bribe
13 physicians and lie to insurers to obtain preauthorization for reimbursement

14 192. Defendant Insys paid prescribers for fake speakers' programs in exchange
15 for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at
16 which the designated speaker did not speak, and, on many occasions, speaker programs at
17 which the only attendees at the events were the speaker and an Insys sales representative. In
18 other words, Insys went beyond just promoting speakers who would, in turn, promote their
19 product: it was a pay-to-prescribe program in which Insys used speakers' programs as a front
20 to pay for prescriptions and to push opioids onto patients who did not need them. These
21 activities are outlined in a complaint filed by the Department of Justice, intervening in five
22 lawsuits that accuse Insys of violating the False Claims Act in connection with the marketing
23 of Subsys.⁸⁷
24

25
26 ⁸⁷ Press Release, Department of Justice, *United States Intervenes in False Claims Act Lawsuits Accusing Insys*
27 *Therapeutics of Paying Kickbacks and Engaging in Other Unlawful Practices to Promote Subsys, A Powerful*

1 193. According to publically available information, payments by Insys included
2 over \$150,000 to Dr. Mahmood Ahmad between 2013 and 2016 for promotional speaking,
3 consulting, and other payments.⁸⁸ Dr. Ahmad operated a pain clinic in Anchorage, Alaska,
4 until his license was suspended by the Alaska State Medical Board due to his dangerous opioid
5 prescribing practices.⁸⁹

7 194. In addition to its fraudulent “speaker program,” Insys established an internal
8 unit, sometimes referred to as the Insys Reimbursement Center, to facilitate the process of
9 obtaining prior authorization of Subsys prescriptions, which is required by many insurers.
10 Insys employees in the Insys Reimbursement Center employed fraudulent and misleading
11 tactics to secure reimbursements, including falsifying medical histories of patients, falsely
12 claiming that patients had cancer, and providing misleading information to insurers regarding
13 patients’ diagnoses and medical conditions. Insys employees also lied about their employer,
14 falsely claiming or implying that they were employed by the physician or nurse practitioner
15 that had prescribed Subsys. Specific examples of this fraudulent conduct are also outlined in
16 the United States’ Complaint in Intervention against Insys.⁹⁰

19 195. All of these actions were intended to, and had the effect of, pushing Insys’s
20 dangerous opioid products onto patients who did not need it.

22 *Opioid Painkiller* (May 15, 2018), available at <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuits-accusing-insys-therapeutics-paying> (providing a link to recently unsealed complaint) (last visited Aug. 10, 2018).

23 ⁸⁸ ProPublica, Dollars for Docs: Talk With Your Doctor, *supra*, note 11.

24 ⁸⁹ Michelle Theriault Boots, *Medical board suspends license of doctor accused of running painkiller ‘pill mill’ clinic in Anchorage*, Anchorage Daily News (f/k/a Alaska Dispatch News), May 24, 2016, <https://www.adn.com/alaska-news/2016/05/23/medical-board-suspends-license-of-doctor-accused-of-running-painkiller-pill-mill-clinic-in-anchorage/> (last visited August 10, 2018).

26 ⁹⁰ *Supra*, note 86.

1 C. All Defendants assisted in the creation of a nationwide, illicit market for opioids
2 by failing to uphold their legal duties to prevent unlawful diversion

3 196. In addition to the allegations above, all Defendants played a role in the
4 creation of an illicit market for prescription opioids, including in the geographic area in Alaska
5 served by the Plaintiff, further fueling the opioid epidemic, by failing to fulfill their legal duties
6 to prevent diversion.

7 197. Opioid “diversion” occurs whenever the supply chain of prescription opioids
8 is broken, allowing drugs to be transferred from a legitimate channel of distribution or use to
9 an illegitimate channel of distribution or use. Opioid diversion occurs at an alarming rate in the
10 United States, and diverted prescription opioids predictably flow across State lines and
11 between jurisdictions throughout the country.

12 198. Each participant in the supply chain, including each Defendant, has a
13 common law duty to prevent diversion by using reasonable care under the circumstances. This
14 includes a duty not to create a foreseeable risk of harm to others. Additionally, one who
15 engages in affirmative conduct and thereafter realizes or should realize that such conduct has
16 created an unreasonable risk of harm to another is under a duty to exercise reasonable care to
17 prevent the threatened harm.

18 199. In addition to their common law duties, Defendants are subject to the
19 statutory requirements of the Controlled Substances Act, 21 U.S.C. §§ 801, *et seq.* (the
20 “CSA”), and its implementing regulations. Congress passed the CSA partly out of a concern
21 about “the widespread diversion of [controlled substances] out of legitimate channels into the
22 illicit market.” H.R. Rep. No. 91-1444, 91st Cong., Sess. 1 (1970), reprinted in U.S.C.C.A.N.
23 4566, 4572.
24
25
26
27

1 200. The CSA imposes a legal framework for the distribution and dispensing of
2 controlled substances. This framework acts as a system of checks and balances from the
3 manufacturing level through delivery of the controlled substance to the patient or ultimate user.

4 201. Every person or entity that manufactures, distributes, or dispenses opioids
5 must obtain a registration with the DEA. Registrants at every level of the supply chain must
6 fulfill their obligations under the CSA.

7 202. All opioid distributors are required to maintain effective controls against
8 opioid diversion. They are required to create and use a system to identify and report to law
9 enforcement downstream suspicious orders of controlled substances, such as orders of
10 unusually large size, orders that are disproportionate, orders that deviate from a normal pattern,
11 and/or orders of unusual frequency. To comply with these requirements, distributors must
12 know their customers, must conduct due diligence, must report suspicious orders, and must
13 terminate orders if there are indications of diversion.

14 203. Under the CSA, anyone authorized to handle controlled substances must
15 track shipments. The DEA's Automation of Reports and Consolidation Orders System
16 (ARCOS) is an automated drug reporting system that records and monitors the flow of
17 Schedule II controlled substances from the point of manufacture through distribution to the
18 point of sale. ARCOS accumulates data on distributors' controlled substances and transactions,
19 which are then used to identify diversion. Each person or entity registered to distribute
20 "ARCOS reportable" controlled substances, including opioids, must report each acquisition
21 and distribution transaction to the DEA. *See* 21 U.S.C. § 827; 21 C.F.R. § 1304.33. Each
22 registrant must also maintain a complete, accurate and current record of each substance
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1 manufactured, imported, received, sold, delivered, exported, or otherwise disposed of.

2 204. Each registrant must also comply with the security requirements to prevent
3 diversion set forth in 21 C.F.R. § 1301.71.

4 1. The Distributor Defendants' failure to prevent diversion

5 205. The DEA has provided guidance to distributors on how to combat opioid
6 diversion. On information and belief, since 2006 the DEA has conducted one-on-one briefings
7 with distributors regarding downstream customer sales, due diligence, and regulatory
8 responsibilities. On information and belief, the DEA also provides distributors with data on
9 controlled substance distribution patterns and trends, including data on the volume and
10 frequency of orders and the percentage of controlled versus non-controlled purchases. On
11 information and belief, the DEA has also hosted conferences for opioid distributors and has
12 participated in numerous meetings and events with trade associations.

13 206. On September 27, 2006, and December 27, 2007, the DEA Office of
14 Diversion Control sent letters to all registered distributors providing guidance on suspicious
15 order monitoring and the responsibilities and obligations of registrants to prevent diversion.

16 207. As part of the legal obligation to maintain effective controls against
17 diversion, the distributor is required to exercise due care in confirming the legitimacy of each
18 and every order prior to filling. Circumstances that could be indicative of diversion include
19 ordering excessive quantities of a limited variety of controlled substances while ordering few if
20 any other drugs; ordering a disproportionate amount of controlled substances versus non-
21 controlled prescription drugs; ordering excessive quantities of a limited variety of controlled
22 substances in combination with lifestyle drugs; and ordering the same controlled substance
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1 from multiple distributors.

2 208. Suspicious orders must be reported when discovered. Registrants must
3 perform an independent analysis of a suspicious order prior to the sale to determine if the
4 controlled substances would likely be diverted, and filing a suspicious order and then
5 completing the sale does not absolve the registrant from legal responsibility.
6

7 209. On information and belief, the Distributor Defendants' own industry group,
8 the Healthcare Distribution Management Association (HDMA), now known as the Healthcare
9 Distribution Alliance (HDA), published Industry Compliance Guidelines titled "Reporting
10 Suspicious Orders and Preventing Diversion of Controlled Substances" emphasizing the
11 critical role of each member of the supply chain in distributing controlled substances. These
12 industry guidelines stated: "At the center of a sophisticated supply chain, distributors are
13 uniquely situated to perform due diligence in order to help support the security of controlled
14 substances they deliver to their customers."⁹¹
15

16 210. Opioid distributors have admitted to the magnitude of the problem and, at
17 least superficially, their legal responsibilities to prevent diversion. They have made statements
18 assuring the public they are supposedly undertaking a duty to curb the opioid epidemic.
19

20 211. These assurances, on their face, of identifying and eliminating criminal
21 activity and curbing the opioid epidemic create a duty for the Distributor Defendants to take
22 reasonable measures to do just that.
23

24 212. Despite their duties to prevent diversion, the Distributor Defendants have
25

26 ⁹¹ HDMA Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled
27 Substances, filed in *Cardinal Health, Inc. v. Holder*, No. 12-5061 (D.C. Cir. Mar. 7, 2012), Doc. No. 1362415 (App.
B at 1).

1 knowingly, recklessly, or negligently allowed diversion.⁹² The DEA has repeatedly taken
2 action to attempt to force compliance, including 178 registrant actions between 2008 and 2012,
3 76 orders to show cause issued by the Office of Administrative Law Judges, and 41 actions
4 involving immediate suspension orders.⁹³ The Distributor Defendants' wrongful conduct and
5 inaction have resulted in numerous civil fines and other penalties, including:
6

- 7 a. In a 2017 Administrative Memorandum of Agreement between McKesson
8 and the DEA, McKesson admitted that it "did not identify or report to [the]
9 DEA certain orders placed by certain pharmacies which should have been
10 detected by McKesson as suspicious based on the guidance contained in the
11 DEA Letters." McKesson was fined \$150,000,000.⁹⁴
12
13 b. McKesson has a history of repeatedly failing to perform its duties. In May
14 2008, McKesson entered into a settlement with the DEA on claims that
15 McKesson failed to maintain effective controls against diversion of
16 controlled substances. McKesson allegedly failed to report suspicious orders
17 from rogue Internet pharmacies around the Country, resulting in millions of
18 doses of controlled substances being diverted. McKesson's system for
19 detecting "suspicious orders" from pharmacies was so ineffective and
20

21
22 ⁹² Scott Higham and Lenny Bernstein, *The Drug Industry's Triumph Over the DEA*, The Wash. Post, Oct. 15, 2017,
23 available at http://wapo.st/opioids?tid=ss_mail (last accessed Aug. 10, 2018); Lenny Bernstein *et al.*, *How drugs*
24 *intended for patients ended up in the hands of illegal users: 'No one was doing their job,'* Wash. Post, Oct. 22,
25 2016, available at http://wapo.st/2etAUdQ?tid=ss_mail&utm_term=.96341c37bdb5 (last accessed Aug. 10, 2018).

26 ⁹³ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement*
27 *Administration's Adjudication of Registrant Actions* 6 (May 2014), available at
<https://oig.justice.gov/reports/2014/e1403.pdf> (last accessed Aug. 10, 2018).

⁹⁴ Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the
McKesson Corp., at 3 (Jan. 17, 2017), available at <https://www.justice.gov/opa/press-release/file/928476/download>
(last accessed Feb. 27, 2018).

dysfunctional that at one of its facilities in Colorado between 2008 and 2013, it filled more than 1.6 million orders, for tens of millions of controlled substances, but it reported just 16 orders as suspicious, all from a single consumer.

- c. On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Auburn, Washington, for failure to maintain effective controls against diversion.
- d. On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Lakeland, Florida, for failure to maintain effective controls against diversion.
- e. On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Swedesboro, New Jersey, for failure to maintain effective controls against diversion.
- f. On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against a Cardinal Health facility in Stafford, Texas, for failure to maintain effective controls against diversion.
- g. In 2008, Cardinal paid a \$34 million penalty to settle allegations about opioid diversion taking place at seven of its warehouses in the United States.⁹⁵

⁹⁵ Lenny Bernstein and Scott Higham, *Cardinal Health fined \$44 million for opioid reporting violations*, The Wash. Post, Jan. 11, 2017, available at http://wapo.st/2j8VHEc?tid=ss_mail&utm_term=.e5b03bdcdf6a (last accessed Feb. 27, 2018).

- 1 h. On February 2, 2012, the DEA issued another Order to Show Cause and
2 Immediate Suspension Order against a Cardinal Health facility in Lakeland,
3 Florida, for failure to maintain effective controls against diversion.
4
5 i. In 2012, Cardinal reached an administrative settlement with the DEA
6 relating to opioid diversion between 2009 and 2012 in multiple states.
7
8 j. In December 2016, the Department of Justice announced a multi-million
9 dollar settlement with Cardinal for violations of the CSA.⁹⁶
10
11 k. On information and belief, in connection with the investigations of Cardinal,
12 the DEA uncovered evidence that Cardinal's own investigator warned
13 Cardinal against selling opioids to a particular pharmacy in Wisconsin that
14 was suspected of opioid diversion. Cardinal did nothing to notify the DEA
15 or cut off the supply of drugs to the suspect pharmacy. Cardinal did just the
16 opposite, pumping up opioid shipments to the pharmacy to almost 2,000,000
17 doses of oxycodone in one year, while other comparable pharmacies were
18 receiving approximately 69,000 doses/year.
19
20 l. In 2007, AmerisourceBergen lost its license to send controlled substances
21 from a distribution center amid allegations that it was not controlling
22 shipments of prescription opioids to Internet pharmacies.
23
24 m. In 2012, AmerisourceBergen was implicated for failing to protect against
25 diversion of controlled substances into non-medically necessary channels.

26 ⁹⁶ Press Release, United States Dep't of Justice, *Cardinal Health Agrees to \$44 Million Settlement for Alleged*
27 *Violations of Controlled Substances Act* (Dec. 23, 2016), available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act> (last accessed Aug. 10, 2018).

1 n. In 2016, five drug wholesalers, including Anda, agreed to a \$4.2 million
2 settlement in connection with a lawsuit alleging that they shipped an
3 excessive number of prescription opioids in West Virginia.⁹⁷ Anda's share is
4 \$1.9 million.
5

6 213. Although distributors have been penalized by law enforcement authorities,
7 these penalties have not changed their conduct. They pay fines as a cost of doing business in an
8 industry that generates billions of dollars in revenue and profit.

9 214. The Distributor Defendants' failure to prevent the foreseeable consequences
10 of opioid diversion created an enormous black market for prescription opioids, which market
11 extends to the geographic area and eligible patient population served by the Plaintiff. Each
12 Distributor Defendants knew or should have known that a large amount of the opioids they
13 distributed were not being consumed for medical purposes and that the amount of opioids
14 distributed was far in excess of what could be consumed for medically necessary purposes.
15

16 215. The Distributor Defendants negligently or intentionally failed to adequately
17 control their supply lines to prevent diversion. A reasonably prudent distributor of Schedule II
18 controlled substances would have anticipated the danger of opioid diversion and protected
19 against it by, for example, taking greater care in hiring, training, and supervising employees;
20 providing greater oversight, security, and control of supply channels; looking more closely at
21 the pharmacists and doctors who were purchasing large quantities of commonly abused opioids
22
23

24 ⁹⁷ AP, *5 drug wholesalers agree to settle pill shipment lawsuit*, The Washington Times, June 23, 2016,
25 <https://www.washingtontimes.com/news/2016/jun/23/2-more-drug-wholesalers-settle-in-pill-shipment-la/> (last
26 accessed Aug. 10, 2018); Thomas Sullivan, *More Opioid Pill Shipment Settlements*, Policy & Medicine, May 5,
27 2018 <https://www.policymed.com/2016/07/more-opioid-pill-shipment-settlements.html> (last accessed Aug. 10,
2018).

1 in amounts greater than the populations in those areas would warrant; investigating
2 demographic or epidemiological facts concerning the increasing demand for narcotic
3 painkillers; providing information to pharmacies and retailers about opioid diversion; and in
4 general, simply following applicable statutes, regulations, professional standards, and guidance
5 from government agencies and using a little bit of common sense.
6

7 216. On information and belief, the compensation the Distributor Defendants
8 provided to certain of their employees was affected, in part, by the volume of their sales of
9 opioids to pharmacies and other facilities, thus improperly creating incentives that contributed
10 to and exacerbated opioid diversion and the resulting epidemic of opioid abuse.
11

12 217. It was reasonably foreseeable to the Distributor Defendants that their
13 conduct in flooding the market in the United States and Alaska with highly addictive opioids
14 would allow opioids to fall into the hands of children, addicts, criminals, and other unintended
15 users.
16

17 218. It is reasonably foreseeable to the Distributor Defendants that, when
18 unintended users gain access to opioids, tragic preventable injuries will result, including
19 addiction, overdoses, and death. It is also reasonably foreseeable that many of these injuries
20 will be suffered by individuals served by the Plaintiff, and that the costs of these injuries will
21 thus be borne by the Plaintiff.
22

23 219. The Distributor Defendants knew or should have known that the opioids
24 being diverted from their supply chains would contribute to the opioid epidemic, and would
25 create access to opioids by unauthorized users, which, in turn, perpetuates the cycle of
26 addiction, demand, illegal transactions, economic ruin, and human tragedy.
27

1 220. The Distributor Defendants were aware of widespread prescription opioid
2 abuse in Alaska and the geographic areas served by the Plaintiff, but, on information and
3 belief, they nevertheless persisted in a pattern of distributing commonly abused and diverted
4 opioids in specific geographic areas, in such quantities, and with such frequency, that they
5 knew or should have known these commonly abused controlled substances were not being
6 prescribed and consumed for legitimate medical purposes.
7

8 221. The use of opioids by individuals served by the Plaintiff who were addicted
9 or who did not have a medically necessary purpose could not occur without the knowing
10 cooperation and assistance of the Distributor Defendants. If the Distributor Defendants adhered
11 to effective controls to guard against diversion, the Plaintiff and the population it serves would
12 have avoided significant injury.
13

14 222. The Distributor Defendants made substantial profits over the years based on
15 the diversion of opioids into the United States and Alaska. The Distributor Defendants knew
16 that due to diversion into the geographic areas in Alaska served by the Plaintiff, the Plaintiff
17 would be unjustly forced to bear the costs of these injuries and damages.
18

19 223. The Distributor Defendants' intentional distribution of excessive amounts of
20 prescription opioids throughout the United States and in Alaska showed an intentional or
21 reckless disregard for the safety of the public and the eligible patient population served by the
22 Plaintiff. Their conduct poses a continuing threat to this population, and therefore to the
23 Plaintiff.
24

25 2. The Manufacturer Defendants' failure to prevent diversion

26 224. The same legal duties to prevent diversion and to monitor, report, and
27

1 prevent suspicious orders of prescriptions opioids that were incumbent upon the Distributor
2 Defendants were also legally required of the Manufacturer Defendants under federal law.

3 225. Like the Distributor Defendants, the Manufacturer Defendants are required to
4 design and operate a system to detect suspicious orders, and to report such orders to law
5 enforcement. *See* 21 C.F.R. § 1301.74(b); 21 U.S.C. § 823. The Manufacturer Defendants have
6 not done so.

7
8 226. On information and belief, for over a decade the Manufacturer Defendants
9 have been able to track the distribution and prescribing of their opioids down to the retail and
10 prescriber level. Thus, the Manufacturer Defendants had actual knowledge of the prescribing
11 practices of doctors, including red flags indicating diversion. The Manufacturer Defendants did
12 not report those red flags, nor did they cease marketing to those doctors. Like the Distributor
13 Defendants, the Manufacturer Defendants breached their duties under federal law.

14
15 227. The Manufacturer Defendants had access to and possession of the
16 information necessary to monitor, report, and prevent suspicious orders and to prevent
17 diversion. In addition to tracking prescriptions, the Manufacturer Defendants engaged in the
18 practice of paying “chargebacks” to opioid distributors. A chargeback is a payment made by a
19 manufacturer to a distributor after the distributor sells the manufacturer’s product at a price
20 below a specified rate. After a distributor sells a manufacturer’s product to a pharmacy, for
21 example, the distributor requests a chargeback from the manufacturer and, in exchange for the
22 payment, the distributor identifies to the manufacturer the product, volume and the pharmacy to
23 which it sold the product. Thus, the Manufacturer Defendants knew the volume, frequency, and
24 pattern of opioid orders being placed and filled. The Manufacturer Defendants built receipt of
25
26
27

1 this information into the payment structure for the opioids provided to the opioid distributors.

2 228. The Department of Justice has recently confirmed the suspicious order
3 obligations clearly imposed by federal law (21 C.F.R. § 1301.74(b); 21 U.S.C. § 823(a)(1)),
4 fining Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances,
5 including opioids, and for violating recordkeeping requirements.⁹⁸ Among the allegations
6 resolved by the settlement, the government alleged “Mallinckrodt failed to design and
7 implement an effective system to detect and report suspicious orders for controlled substances –
8 orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied
9 distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an
10 increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious
11 orders.”⁹⁹ Mallinckrodt agreed that its “system to monitor and detect suspicious orders did not
12 meet the standards outlined in letters from the DEA Deputy Administrator, Office of Diversion
13 Control, to registrants dated September 27, 2006 and December 27, 2007.”¹⁰⁰

14 229. Purdue also unlawfully and unfairly failed to report or address illicit and
15 unlawful prescribing of its drugs, despite knowing about it for years. Through its extensive
16 network of sales representatives, Purdue had and continues to have knowledge of the
17 prescribing practices of thousands of doctors and could identify doctors who displayed red flags
18 for diversion such as those whose waiting rooms were overcrowded, whose parking lots had
19
20
21
22

23 ⁹⁸ See Press Release, U.S. Dep’t of Justice, *Mallinckrodt Agrees to Pay Record \$35 Million Settlement for Failure to*
24 *Report Suspicious Orders of Pharmaceutical Drugs and for Recordkeeping Violations* (July 11, 2017),
[https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders)
25 [orders](https://www.justice.gov/opa/pr/mallinckrodt-agrees-pay-record-35-million-settlement-failure-report-suspicious-orders).

26 ⁹⁹ *Id.* (internal quotations omitted).

27 ¹⁰⁰ Administrative Memorandum of Agreement between the United States Dep’t of Justice, the Drug Enforcement
Agency, and Mallinckrodt, plc. and its subsidiary Mallinckrodt, LLC (July 10, 2017), [https://www.justice.gov/usao-](https://www.justice.gov/usao-edmi/press-release/file/986026/download)
[edmi/press-release/file/986026/download](https://www.justice.gov/usao-edmi/press-release/file/986026/download).

1 numerous out-of-state vehicles, and whose patients seemed young and healthy or homeless.

2 230. Using this information, Purdue has maintained a database since 2002 of
3 doctors suspected of inappropriately prescribing its drugs.¹⁰¹ Rather than report these doctors to
4 state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or
5 cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of
6 OxyContin—the same OxyContin that Purdue had promoted as less addictive—in order to
7 persuade the FDA to bar the manufacture and sale of generic copies of the drug because the
8 drug was too likely to be abused.

9
10 231. In an interview with the Los Angeles Times,¹⁰² Purdue's senior compliance
11 officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to
12 take action—even where Purdue employees personally witnessed the diversion of its drugs. The
13 same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report
14 until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1
15 million OxyContin tablets and that Purdue's district manager described internally as “an
16 organized drug ring.” In doing so, Purdue protected its own profits at the expense of public
17 health and safety.

18
19 232. In 2016, the NY AG found that, between January 1, 2008 and March 7, 2015,
20 Purdue's sales representatives, at various times, failed to timely report suspicious prescribing
21

22
23 ¹⁰¹ Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, Aug. 11,
24 2013, available at <http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811> (last accessed Aug. 13,
2018).

25 ¹⁰² Harriet Ryan et al., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the*
26 *drugmaker knew*, L.A. Times, July 10, 2016, available at <http://www.latimes.com/projects/la-me-oxycontin-part2/>
27 (last accessed Aug. 13, 2018).

1 and continued to detail those prescribers even after they were placed on a “no-call” list.”¹⁰³

2 233. As Dr. Mitchell Katz, director of the Los Angeles County Department of
3 Health Services, said in a Los Angeles Times article, “Any drug company that has information
4 about physicians potentially engaged in illegal prescribing or prescribing that is endangering
5 people’s lives has a responsibility to report it.”¹⁰⁴ The NY AG’s settlement with Purdue
6 specifically cited the company for failing to adequately address suspicious prescribing. Yet, on
7 information and belief, Purdue continues to profit from the prescriptions of such prolific
8 prescribers.
9

10 234. Like Purdue, Endo has been cited for its failure to set up an effective system
11 for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the
12 NY AG found that Endo failed to require sales representatives to report signs of abuse,
13 diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing
14 prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to
15 prevent sales representatives from visiting prescribers whose suspicious conduct had caused
16 them to be placed on a no-call list. The NY AG also found that, in certain cases where Endo’s
17 sales representatives detailed prescribers who were convicted of illegal prescribing of opioids,
18 those representatives could have recognized potential signs of diversion and reported those
19 prescribers but failed to do so.
20
21

22 235. On information and belief, the other Manufacturer Defendants have engaged
23

24 ¹⁰³ See Assurance of Discontinuance, *In re Purdue Pharma L.P.* (Assurance No. 15-151), available at
25 <https://ag.ny.gov/pdfs/Purdue-AOD-Executed.pdf> (last visited Aug. 13, 2018).

26 ¹⁰⁴ Scott Glover and Lisa Girion, *OxyContin maker closely guards its list of suspect doctors*, L.A. Times, August 11,
27 2013, available at <http://articles.latimes.com/2013/aug/11/local/la-me-rx-purdue-20130811> (last accessed
Aug. 13, 2018).

1 in similar conduct in violation of their responsibilities to prevent diversion.

2 236. The Manufacturer Defendants' actions and omissions in failing to effectively
3 prevent diversion and failing to monitor, report, and prevent suspicious orders have enabled the
4 unlawful diversion of opioids into the geographic area and eligible patient population served by
5 the Plaintiff.
6

7 3. The Defendants' actions in inflating and flooding the market with
8 prescription opioids, and in failing to prevent diversion, foreseeably led to
9 the flow of such drugs between jurisdictions

10 237. While each of the Defendants do business in the State of Alaska, their
11 activity in that State is not the only conduct that is relevant to the creation of the opioid
12 epidemic in that State or the injury suffered by the Tribal Heath Organizations. Nor does
13 prescription and other specific data from any particular jurisdiction necessarily capture the full
14 scope of the misuse, oversupply, and diversion problem in that area. That is because the
15 Defendants' actions nationwide foreseeably fueled a widespread epidemic in which diverted
16 prescription opioid pills were and are trafficked between jurisdictions to meet the demand
17 created by the Defendants' promotion and distribution of highly addictive, controlled
18 substances. The trafficking of prescription opioids between jurisdictions, which has been
19 documented by law enforcement across the country, was an entirely foreseeable consequence of
20 the Defendants' actions, and Defendants were in fact aware of and profited from it.
21

22 238. In one widely-reported example, 1.1 million OxyContin pills were
23 transported from the Lake Medical pain clinic in Los Angeles and cooperating pharmacies to
24 the City of Everett, Washington, where they were sold on the black market. Couriers drove the
25 pills up I-5 through California and Oregon, or flew from Los Angeles to Seattle. The Everett-
26
27

1 based dealer who received and sold the pills wore a diamond necklace in the shape of the West
2 Coast states, with a trail of green gems—the color of 80-milligram OxyContin pills—
3 connecting Los Angeles and Washington State. At the time, Purdue was aware of the massive
4 and highly suspicious quantities of prescriptions written by Lake Medical’s physicians and
5 filled by area pharmacies, but it did not alert law enforcement until years later.¹⁰⁵ Other such
6 pipelines exist or have existed between other jurisdictions throughout the United States.
7

8 239. The opioid epidemic in Alaska, and in the geographic area served by the
9 Plaintiff, is sustained, in part, by the flow of prescription opioids into the State from other
10 jurisdictions. The most recent Alaska State Troopers Annual Drug Report notes that drug
11 trafficking organizations (“DTOs”) from the Lower 48 have infiltrated Alaska and that “the
12 source of the illicit substances peddled by the major DTOs comes from outside the state.”¹⁰⁶
13 “[H]eroin, prescription opioids, and other drugs make their way to rural Alaska via transport
14 that is not subject to the same level of federal security/inspection as that of major commercial
15 airlines.”¹⁰⁷ This includes trafficking by way bush airlines, small planes, boats and even Alaska
16 Marine Highway System and inter-island ferries, where a recent sweep by the United States
17 Coast Guard and the Alaska State Troopers resulted in the seizure of illegal prescription drugs,
18 among other contraband.¹⁰⁸ The ferry system serves Southeast Alaska, including many of the
19
20
21

22 ¹⁰⁵ See Harriet Ryan et al., *How black-market OxyContin spurred a town’s descent into crime, addiction and*
heartbreak, L.A. Times (July 10, 2016), available at <http://www.latimes.com/projects/la-me-oxycontin-everett/>.

23 ¹⁰⁶ Alaska State Troopers Annual Drug Report (2016), <https://dps.alaska.gov/getmedia/f259530b-5277-408e-9d45-4999958fe530/2016-Annual-Drug-Report-6-28-17final.aspx>.

24 ¹⁰⁷ Alaska Opioid Policy Taskforce, Final Recommendations, 2017, page 4, available at
<http://dhss.alaska.gov/AKOpioidTaskForce/Documents/AOPTF-Recommendations-1-19-17.pdf>. Note: this taskforce
25 included participation by Tina Woods, PhD, Alaska Native Tribal Health Consortium.

26 ¹⁰⁸ See Liz Thomas, *Marine Highway operation leads to meth, heroin seizures*, KTVB (July 6, 2018), available at
<http://www.ktvb.com/story/38590945/marine-highway-operation-leads-to-meth-heroin-seizures>.

1 communities served by the Plaintiff.

2 240. Such diversion and trafficking of prescription opioid drugs manufactured and
3 distributed by Defendants is a direct and foreseeable consequence of their intentional conduct in
4 inflating the market for their highly addictive drugs across the country, and then flooding that
5 market through the distribution of large quantities of those drugs while ignoring “red flags” and
6 flouting the very laws and regulations designed to prevent unlawful diversion.
7

8 D. Defendants’ unlawful conduct and breaches of legal duties caused harm and
9 substantial damages to the Plaintiff

10 241. Defendants’ actions, including false and misleading advertising and a failure
11 to prevent diversion, have fueled a new wave of addiction and injury throughout the United
12 States and in the geographic area and eligible patient population served by the Plaintiff. As the
13 Manufacturer Defendants’ efforts to expand the market for opioids increased, so have the rates
14 of prescription and sale of their products—and the rates of opioid-related substance abuse,
15 hospitalization, and death among the people of the United States and Alaska. The Distributor
16 Defendants have continued to unlawfully ship massive quantities of these drugs throughout the
17 United States, knowing that a substantial portion were being diverted and feeding the
18 nationwide opioid epidemic.
19

20 242. Defendants repeatedly and purposefully breached their duties under state and
21 federal law, and such breaches are direct and proximate causes of, and/or substantial factors
22 leading to, the widespread overuse, misuse, and diversion of prescription opioids across the
23 Nation, throughout Alaska, and in the geographic area and eligible patient population served by
24 the Plaintiff.
25

26 243. There is a “parallel relationship between the availability of prescription
27

1 opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these
2 drugs and associated adverse outcomes.”¹⁰⁹

3 244. For example, reflecting the increase in opioid supply and demand, dosage
4 units of OxyContin and generic oxycodone seized by law enforcement in Alaska increased from
5 1,183 in 2014 to 4,552 in 2016.¹¹⁰

6
7 245. Further, because of the well-established relationship between the use of
8 prescription opioids and the use of non-prescription opioids, such as heroin, the massive
9 distribution of prescription opioids throughout the United States and Alaska has caused an
10 opioid epidemic that includes heroin addiction, abuse, and death. According to the National
11 Institute of Health’s National Institute on Drug Abuse, about 80 percent of people who use
12 heroin first misused prescription opioids.¹¹¹ Many patients presenting to the Plaintiff who are
13 abusing opioids, including heroin, first became addicted as the result of a legitimate
14 prescription.
15

16 246. Heroin is one of the primary substances abused by Alaskans, and both
17 prescription opiate abuse and availability of synthetic opioids, such as fentanyl, are on the rise
18 in Alaska. The most recent Alaska State Troopers Annual Drug Report concludes, “The
19 producers of synthetic opioids are essentially piggybacking on the market created from
20 prescription medication diversion as well as increase [in] the volume and profits on heroin.” The
21 Report notes at least 122 overdose deaths due to heroin and synthetic opioids in Alaska between
22
23

24 ¹⁰⁹ Richard C. Dart, et al., *Trends in Opioid Analgesic Abuse and Mortality in the United States*, 372 N. Engl. J.
25 Med. 241 (2015), <https://www.nejm.org/doi/full/10.1056/NEJMsa1406143>.

¹¹⁰ *Alaska State Troopers Annual Drug Report*, *supra* note 106, at 13.

26 ¹¹¹ See National Institute on Drug Abuse, NIH, *Opioid Overdose Crisis* (Revised March 2018),
<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#seven>.

January 1, 2014 through September 15, 2016.

247. Among Alaska Natives, there were 52 deaths with underlying or contributing cause listed as opioids between 2014 and 2016.¹¹² On information and belief, many of those Alaska Natives who died, and the members of their families who also need additional services as a result, are part of the population served by the Plaintiff:

Mortality: Alaska Native Deaths (2014-2016)				
52 deaths with underlying or contributing cause listed as opioids.				
Age Group	Drug	Type	Deaths	Proportion
15-24	Heroin	Illegal Street Drug	8	67%
	Opioids	Prescription	2	
	Methadone	Addiction Treatment	1	
	Synthetic	Very dangerous	1	
	Total		12	
25-44	Heroin	Illegal Street Drug	15	56%
	Opioids	Prescription	9	33%
	Methadone	Addiction Treatment	3	
	Total		27	
45-64	Heroin	Illegal Street Drug	3	
	Opioids	Prescription	8	67%
	Methadone	Addiction Treatment	1	
	Total		12	

Figure 1¹¹³

¹¹² Presentation by Gretchen Day, Alaska Native Tribal Health Consortium Clinical & Research Services, and Erin Semmens, University of Montana, "Data Indicators of Opioid Use in Alaska and Montana at the American Indian Alaska Native Clinical and Traditional Research Program Opioid Research Symposium, slide 10, March 29, 2018.

¹¹³ *Id.* slide 11.



Mortality: Alaska Native Opioid-Related Deaths (1999-2016)



Figure 2¹¹⁴

248. Opioid-related deaths represent only the tip of the iceberg. The Plaintiff has treated and continues to treat numerous patients with opioid-related conditions, including overdose, addiction, and other related conditions.

249. At the Mt. Edgecumbe Hospital in Sitka, operated by Plaintiff, Emergency Department visits involving opioid abuse and/or dependence have dramatically increased since the early 2000s, with a high of fifteen such admissions in 2017 and eight so far in 2018, as compared with an average of 1-3 such visits between 2000 and 2007. The Mt. Edgecumbe

¹¹⁴ *Id.* slide 10.

1 Hospital is a critical access facility serving most of Southeast Alaska and serves as a regional
2 referral hospital for Plaintiff's rural primary care clinics.

3 250. Although Plaintiff has taken measures to curb opioid prescribing rates at its
4 facilities in recent years, and has discontinued the use of certain name-brand opioids including
5 OxyContin, patients nevertheless have informed providers at those facilities that they are able to
6 obtain prescription opioids, as well as illegal opioid drugs, "on the street" if they cannot obtain
7 them directly from Plaintiff.
8

9 251. The Plaintiff has incurred a wide range of costs associated with the treatment
10 of these opioid-affected patients.
11

12 252. These increased costs include costs of treating addictions, through behavioral
13 health programs and Medication Assisted Treatment (MAT) Services. For example, Plaintiff
14 has provided MAT Services since 2013 in its Sitka Behavioral Health Clinic, to address
15 Alaska's opioid epidemic by using the most effective FDA approved medications alongside
16 evidence-based practices services. However, Plaintiff's medical staff has estimated 1,400
17 individuals have a need for treatment for substance use disorder and/or serious mental illness,
18 based on the number of opiates that are being dispensed from local pharmacies. Plaintiff
19 foresees the need to expand these programs to communities, like Juneau, as opioid use appears
20 to be increasing in the communities it serves. The drugs used to treat addiction in these types of
21 programs are expensive, ranging from \$80 - \$1300 per patient per month, depending on the drug
22 and the dosage.
23
24

25 253. In addition to treatment for addiction, treatment costs associated with the
26 opioid epidemic include, but are not limited to, costs for treating Hepatitis C and other
27

infections due to intravenous drug use by addicted patients.

254. Opioid abuse has other ripple effects impacting the Plaintiff. For example, Neonatal Abstinence Syndrome (NAS) is increasing nationally and in Alaska. The statewide NAS rate increased more than five-fold during 2001–2012, from less than one to more than five for every 1,000 live births.¹¹⁵ During this period, the average NAS rates were highest among residents of the Municipality of Anchorage and the Southeast region, which is served by Plaintiff (3.6 and 3.4 per 1,000 births, respectively).¹¹⁶

255. In 2017, the rate of newborns statewide with NAS continued to increase, from 8 newborns per 1000 births in the first quarter, to 22 newborns per 1000 births in the last quarter.¹¹⁷ From December 2016 to December 2017, 30.8% of newborns born with NAS were American Indian or Alaska Native.

256. Treatment for NAS is incredibly expensive. Most NAS infants are immediately transferred to a neonatal intensive care unit for a period of days, weeks, or even months. In a national analysis based on data from the Kids' Inpatient Database, between 2003 and 2012, NAS admissions increased more than fourfold, resulting in a surge in annual costs from \$61 million and 67,869 hospital days in 2003 to nearly \$316 million and 291,168 hospital days in 2012. For an infant affected by NAS, the hospital stay was nearly 3.5 times as long (16.57 hospital days compared with 4.98 for a non-NAS patient) and the costs were more than

¹¹⁵ State of Alaska Epidemiology Bulletin, DHHS, *Increase in Neonatal Abstinence Syndrome, Alaska, 2001–2015*, No. 5, Feb. 22, 2016 available at <http://epibulletins.dhss.alaska.gov/Document/Display?DocumentId=1811> (last accessed Aug. 13, 2018). This data is based on all hospital births, which may still miss some newborns.

¹¹⁶ *Id.*

¹¹⁷ Division of Public Health, Alaska DHHS, *Alaska Opioid Data Dashboard*, <http://dhss.alaska.gov/dph/Director/Pages/heroin-opioids/data.aspx> board (select Neonatal Abstinence Syndrome) (last visited Aug. 13, 2018).

1 three times greater (\$16,893 compared to \$5,610 for a non-affected infant).¹¹⁸ These per-patient
2 costs are likely much higher in Alaska, and the area served by the Plaintiff.

3 257. NAS can also require an emergency evacuation for care to save the infant's
4 life. Thus, even when the Plaintiff cannot or does not treat infants with NAS, it often incurs
5 transportation costs associated with transferring them and/or their mothers to appropriate
6 facilities.
7

8 258. Many NAS infants have short-term and long-term developmental issues that
9 prevent them from meeting basic cognitive and motor-skills milestones. Many will suffer from
10 vision and digestive issues; some are unable to attend full days of school. These disabilities
11 follow these children through elementary school and beyond, and may necessitate ongoing
12 treatment that also results in additional costs to the Plaintiff.
13

14 259. Further, the Plaintiff has incurred and continues to incur increased health
15 care costs relating to surgical procedures and other care that is made more complex and
16 expensive than would otherwise be the case if the patients were not opioid addicts. For example,
17 surgical procedures on opioid addicts can require special protective measures and related
18 prescription drugs. In addition, patients with a history of opioid abuse may need procedures that
19 would not otherwise normally be necessary for patients in this age range.
20

21 260. The Plaintiff has also faced increased operational costs relating to dealing
22 with opioid users who present themselves to the Plaintiff claiming to have illnesses and medical
23 problems, which are actually pretexts for obtaining opioids for illicit use, and a need to increase
24

25 ¹¹⁸ Corr TE, Hollenbeak CS. The economic burden of neonatal abstinence syndrome in the United States.
26 *Addiction*. 2017 Sep;112(9):1590-1599. doi: 10.1111/add.13842. Epub 2017 Jun 13, *available at*
27 <https://www.ncbi.nlm.nih.gov/pubmed/28612362> (last visited Aug. 13 2018).

1 security in response to break-ins and other concerns. As one example, Plaintiff recently
2 purchased nine higher-security dispensing cabinets for opioids, costing \$21,000 per cabinet.

3 261. Opioid diversion also contributes to a range of social problems including
4 physical and mental consequences, crime, delinquency, and mortality. The Plaintiff also
5 provides behavioral health services, including but not limited to substance abuse prevention and
6 counseling, domestic violence prevention, suicide prevention, and other related services, and
7 have incurred increased costs in the provision of these services as a result of the opioid
8 epidemic.
9

10 262. In addition to direct treatment costs, the Plaintiff has incurred overhead and
11 programmatic costs necessary to address and abate the crisis. Plaintiff has created various
12 opioid review committees made up of physicians, psychiatrists, nurses, physical therapists,
13 pharmacists and sometimes dentists. These committees meet monthly to review the patients on
14 chronic pain contracts. Plaintiff also devotes resources and staff time to pill counts, urine drug
15 screens, chart reviews, and similar activities in order to continuously monitor patients being
16 treated for pain and to help prevent drug diversion.
17
18

19 263. The Plaintiff has also been required to provide additional staff training, with
20 associated costs. In order to treat a patient with opioid addiction by prescribing suboxone, for
21 example, a prescriber needs a DEA prescribing number, which involves additional education.
22

23 264. Further, the Plaintiff's staff has expended time and resources applying for
24 grants to help address the opioid epidemic.

25 265. The staff hours required for these activities, as well as the costs associated
26 with the care and services described above, divert resources away from other health priorities
27

1 that the Plaintiff is responsible for addressing, like general behavioral health needs, and tobacco
2 and alcohol prevention programs. Further, at least a portion of the diverted funds could have
3 otherwise been used to provide care and services that are reimbursed by third party payors.

4
5 266. It was entirely foreseeable that healthcare providers such as the Plaintiff
6 would need to incur such costs in response to the widespread overuse and misuse of opioids in
7 the geographic areas and patient populations they serve, as precipitated by Defendants' actions
8 alleged herein.

9
10 267. Because many of the Plaintiff's patients are IHS beneficiaries or otherwise
11 exempt from full payment for services, a significant portion of the costs of their medical care
12 are the direct responsibility of the Plaintiff rather than the patient. Further, many of these costs
13 incurred by the Plaintiff go unreimbursed, either because the patient is not covered by insurance
14 or another third party payor, or because the third party payor does not reimburse the full costs of
15 the provided services and/or because the patient is exempt from cost sharing that would
16 otherwise apply.

17
18 268. Additionally, as health care providers, the Plaintiff has purchased and
19 continues to purchase and administer opioids marketed and sold by Defendants, and was and
20 continues to be recipients of the widespread misinformation campaign by the Manufacturer
21 Defendants alleged in this Complaint. The Defendants have marketed and continue to market
22 their opiate products to health care providers throughout the country and Alaska, using
23 various means. The Plaintiff thus was and is a direct customer and victim of the Defendants'
24 false, deceptive, widespread and unfair marketing of opioids.

25 269. Defendants' intentional and/or unlawful conduct aimed at increasing sales
26
27

1 and distribution of opioids resulted in direct, foreseeable, past and continuing economic
2 damages to the Plaintiff, and for which the Plaintiff seeks relief, as alleged herein.

3 270. The Plaintiff needs additional resources to fully abate the crisis, including but
4 not limited to: increased funding for naloxone, drug “takeback” sites and programs, drug
5 disposal bags, and community prevention programming, among other measures.
6

7 271. Having profited enormously through the aggressive sale, misleading
8 promotion, and irresponsible distribution of opioids, Defendants should be required to take
9 responsibility for the financial burdens their conduct has imposed upon the Plaintiff and for the
10 costs of abatement of the crisis.
11

12 E. The statutes of limitations are tolled and Defendants are estopped from asserting
13 statutes of limitations as defenses

14 1. Continuing Conduct

15 272. Defendants’ conduct as described in this Complaint is still ongoing, and the
16 Plaintiff continues to suffer harm from the Defendants’ unlawful actions.

17 273. The continued tortious and unlawful conduct by the Defendants causes a
18 repeated or continuous injury. The damages have not occurred all at once but have continued to
19 occur and have increased as time progresses. The tort is not completed nor have all the damages
20 been incurred until the wrongdoing ceases. The wrongdoing and unlawful activity by
21 Defendants has not ceased. The public nuisance remains unabated. The conduct causing the
22 damages remains unabated.
23

24 2. Equitable Estoppel and Fraudulent Concealment

25 274. Defendants are equitably estopped from relying upon a statute of limitations
26 defense because they undertook efforts to purposefully conceal their unlawful conduct and
27

1 fraudulently assure the public, including the Plaintiff, that they were undertaking efforts to
2 comply with their obligations under the controlled substances laws. Notwithstanding the
3 allegations set forth above, the Defendants affirmatively assured the public and the Plaintiff that
4 they are working to curb the opioid epidemic.
5

6 275. The Defendants were deliberate in taking steps to conceal their conspiratorial
7 behavior and active role in the deceptive marketing and the oversupply of opioids through
8 overprescribing and suspicious sales, all of which fueled the opioid epidemic.

9 276. Specifically, as described above, the Manufacturer Defendants deliberately
10 worked through Front Groups purporting to be patient advocacy and professional organizations,
11 through public relations companies hired to work with the Front Groups and through paid KOLs
12 to secretly control messaging, influence prescribing practices, and drive sales. The Manufacturer
13 Defendants concealed their role in shaping, editing, and approving the content of prescribing
14 guidelines, informational brochures, KOL presentations, and other false and misleading
15 materials addressing pain management and opioids that were widely disseminated to regulators,
16 prescribers, and the public at large. They manipulated scientific literature and promotional
17 materials to make it appear that misleading statements about the risks, safety, and superiority of
18 opioids were actually accurate, truthful, and supported by substantial scientific evidence.
19 Through their public statements, omissions, marketing, and advertising, the Manufacturer
20 Defendants' deceptions deprived the Plaintiff of actual or implied knowledge of facts sufficient
21 to put Plaintiff on notice of potential claims.
22
23
24

25 277. All Defendants concealed the existence of the Plaintiff's claims against them
26 by hiding their lack of cooperation with law enforcement and affirmatively seeking to convince
27

1 the public that their legal duties to report suspicious sales had been satisfied through public
2 assurances that they were working to curb the opioid epidemic. They publicly portrayed
3 themselves as committed to working diligently with law enforcement and others to prevent
4 diversion of these dangerous drugs and curb the opioid epidemic, and they made broad promises
5 to change their ways, insisting they were good corporate citizens. These repeated
6 misrepresentations misled regulators, prescribers, and the public (including the Plaintiff), and
7 deprived the Plaintiff of actual or implied knowledge of the Defendants' role in the opioid
8 epidemic and of facts sufficient to put them on notice of potential claims against the Defendants.

9
10 278. For example, a Cardinal executive claimed that it uses "advanced analytics"
11 to monitor its supply chain, and assured the public it was being "as effective and efficient as
12 possible in constantly monitoring, identifying, and eliminating any outside criminal activity."¹¹⁹

13
14 279. Similarly, McKesson publicly stated that it has a "best-in-class controlled
15 substance monitoring program to help identify suspicious orders," and claimed it is "deeply
16 passionate about curbing the opioid epidemic in our country."¹²⁰

17
18 280. Distributor Defendants, through their trade associations, filed an amicus brief
19 that represented that Defendants took their duties seriously, complied with their statutory and
20 regulatory responsibilities, and monitored suspicious orders using advanced technology.¹²¹

21
22 ¹¹⁹ Lenny Bernstein et al., *How drugs intended for patients ended up in the hands of illegal users: "No one was
23 doing their job,"* The Wash. Post (Oct. 22, 2016), available at
http://wapo.st/2etAUdQ?tid=ss_mail&utm_term=.f455a35fdee5 (last accessed Aug. 13, 2018).

24 ¹²⁰ Scott Higham et al., *Drug industry hired dozens of officials from the DEA as the agency tried to curb opioid
25 abuse,* The Wash. Post, Dec. 22, 2016, available at
http://wapo.st/2hKYW3y?tid=ss_mail&utm_term=.bdac6eb4ec17 (last accessed Aug. 13, 2018).

26 ¹²¹ Brief for Healthcare Distribution Mgmt. Ass'n and Nat'l Ass'n of Chain Drug Stores as *Amici Curiae* in Support
27 of Neither Party, *Masters Pharm, Inc. v. U.S. Drug Enf't Admin.* (No. 15-1335), 2016 WL 1321983, at *3-4, *25.
(D.C. Cir. Apr. 4, 2016).

1 281. Defendants have also concealed and prevented discovery of information,
2 including data from the ARCOS database that will confirm their identities and the extent of their
3 wrongful and illegal activities.

4 282. Defendants also lobbied Congress and actively attempted to halt DEA
5 investigations and enforcement actions and to subvert the ability of agencies to regulate their
6 conduct.¹²² As a result, there was a sharp drop in enforcement actions and the standard for the
7 DEA to revoke a distributor's license was raised.

8 283. Because the Defendants concealed the facts surrounding the opioid epidemic,
9 the Plaintiff did not know of the existence or scope of the Defendants' misconduct, and could
10 not have acquired such knowledge earlier through the exercise of reasonable diligence.

11 284. Defendants knew that their conduct was deceptive, as evidenced by the
12 governmental warnings, actions, and prosecutions alleged throughout this Complaint.

13 285. Defendants intended that their false and deceptive statements and omissions
14 be relied upon, including by the Plaintiff, its member entities, and the communities and patients
15 served by the Plaintiff. The Plaintiff reasonably relied on these statements and omissions.

16 286. Defendants cannot claim prejudice due to a late filing because this suit was
17 filed upon discovering the facts essential to the claim, which Defendants themselves
18 intentionally concealed. Indeed, the existence, extent, and damage of the opioid crisis have only
19 recently come to light.

20 287. The Plaintiff was unable to obtain vital information regarding these claims

21 ¹²² See Higham and Bernstein, *supra* note 92.

absent any fault or lack of diligence on their part.

F. Facts Pertaining to Claims Under RICO

288. Defendants did not simply scheme to market opioids through misrepresentations and turning a blind eye to diversion. Various groups of Defendants also formed informal associations with others (Enterprises) and used these Enterprises to perpetrate their schemes, as described below. The Plaintiff also realleges all preceding paragraphs of this Complaint, which are incorporated herein in their entirety.

1. The Opioid Marketing Enterprise

a. The Common Purpose and Scheme of the Opioid Marketing Enterprise

289. Knowing that their products were highly addictive, ineffective and unsafe for the treatment of long-term chronic pain, non-acute and non-cancer pain, the Manufacturing Defendants formed an association-in-fact enterprise and engaged in a scheme to unlawfully increase their profits and sales, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term chronic pain.

290. In order to unlawfully increase the demand for opioids, the Manufacturing Defendants formed an association-in-fact enterprise (the “Opioid Marketing Enterprise”) with the Front Groups and KOLs described above. Through their personal relationships, the members of the Opioid Marketing Enterprise had the opportunity to form and take actions in furtherance of the Opioid Marketing Enterprise’s common purpose. The Manufacturing Defendants’ substantial financial contribution to the Opioid Marketing Enterprise, and the advancement of opioid-friendly messaging, fueled the U.S. opioid epidemic.

1 291. The Manufacturing Defendants, through the Opioid Marketing Enterprise,
2 concealed the true risks and dangers of opioids from the medical community and the public,
3 including the Plaintiff and the people it serves, and made misleading statements and
4 misrepresentations about opioids that downplayed the risk of addiction and exaggerated the
5 benefits of opioid use. The misleading statements included the following: (1) that addiction is
6 rare among patients taking opioids for pain; (2) that addiction risk can be effectively managed;
7 (3) that symptoms of addiction exhibited by opioid patients are actually symptoms of an
8 invented condition the Manufacturer Defendants named “pseudoaddiction”; (4) that withdrawal
9 is easily managed; (5) that increased dosing presents no significant risks; (6) that long-term use
10 of opioids improves function; (7) that the risks of alternative forms of pain treatment are
11 greater than the adverse effects of opioids; (8) that use of time-released dosing prevents
12 addiction; and (9) that abuse-deterrent formulations provide a solution to opioid abuse.
13

14
15 292. The misleading statements not only caused and worsened the opioid
16 epidemic, but as time went on, they concealed the Manufacturer Defendants’ wrongdoing from
17 the public and the Plaintiff (including as a result of the Opioid Marketing Enterprise).
18

19 293. The scheme devised, implemented, and conducted by the Manufacturer
20 Defendants constituted a common course of conduct designed to ensure that the Manufacturer
21 Defendants unlawfully increased their sales and profits through concealment and
22 misrepresentations about the addictive nature and effectiveness of their drugs. The
23 Manufacturer Defendants, the Front Groups, and the KOLs acted together for a common
24 purpose and perpetrated the Opioid Marketing Enterprise’s scheme, including through the
25 unbranded promotion and marketing network as described above.
26
27

1 294. There was regular communication among the Manufacturer Defendants,
2 Front Groups, and KOLs, in which information was shared, misrepresentations were
3 coordinated, and payments were exchanged. Typically, the coordination, communication, and
4 payment occurred, and continues to occur, through the repeated and continuing use of interstate
5 wires and mail in which the Manufacturer Defendants, Front Groups, and KOLs shared
6 information regarding overcoming objections and resistance to the use of opioids for chronic
7 pain. The Manufacturer Defendants, Front Groups, and KOLs functioned as a continuing unit
8 for the purpose of implementing the Opioid Marketing Enterprise's scheme and common
9 purpose, and each agreed and took actions to hide the scheme and continue its existence. These
10 actions were effective to conceal the scheme and the Opioid Marketing Enterprise and its
11 impact from the Plaintiff until sufficient information came to light due to government and
12 media investigation to allow the Plaintiff to discover it, leading to the filing of the Complaint in
13 this matter.
14

15
16 295. At all relevant times, the Front Groups were aware of the Manufacturer
17 Defendants' conduct and were knowing and willing participants in and beneficiaries of that
18 conduct. Each Front Group also knew, but did not disclose, that the other Front Groups were
19 engaged in the same scheme, to the detriment of consumers, prescribers, and the Plaintiff. But
20 for the Opioid Marketing Enterprise's scheme, the Front Groups would have had incentive to
21 disclose the deceit by the Manufacturer Defendants and the Opioid Marketing Enterprise to
22 their members and constituents. By failing to disclose this information, Front Groups
23 perpetuated the Opioid Marketing Enterprise's scheme and common purpose, continued its
24 wrongful concealment from the Plaintiff, and reaped substantial benefits.
25
26
27

1 296. At all relevant times, the KOLs were aware of the Manufacturer
2 Defendants' conduct and were knowing and willing participants in and beneficiaries of that
3 conduct. The Manufacturer Defendants selected KOLs because they favored the aggressive
4 treatment of chronic pain with opioids. The Manufacturer Defendants' support helped the
5 KOLs become respected industry experts. As they rose to prominence, the KOLs falsely
6 promoted the benefits of using opioids to treat chronic pain, repaying the Manufacturer
7 Defendants by advancing their marketing goals. The KOLs also knew, but did not disclose, that
8 the other KOLs and Front Groups were engaged in the same scheme, to the detriment of
9 consumers, prescribers, and the Plaintiff. But for the Opioid Marketing Enterprise's scheme,
10 the KOLs would have had incentive to disclose the deceit by the Manufacturer Defendants and
11 the Opioid Marketing Enterprise, and to protect their patients and the patients of other
12 physicians. By failing to disclose this information, the KOLs furthered the Opioid Marketing
13 Enterprise's scheme and common purpose, continued its wrongful concealment from the
14 Plaintiff, and reaped substantial benefits.

15
16
17 297. As public scrutiny and media coverage focused on how opioids ravaged
18 communities throughout the United States, the Front Groups and KOLs did not challenge the
19 Manufacturer Defendants' misrepresentations, seek to correct their previous
20 misrepresentations, terminate their role in the Opioid Marketing Enterprise, nor disclose
21 publicly that the risks of using opioids for chronic pain outweighed their benefits and that the
22 use of opioids for chronic pain was not supported by medically acceptable evidence. The
23 Manufacturer Defendants and their co-conspirators thus continued to conceal the Manufacturer
24 Defendants' wrongdoing from the Plaintiff.
25
26
27

1 *b. The Conduct of the Opioid Marketing Enterprise*

2 298. The Manufacturer Defendants, Front Groups, and KOLs engaged in certain
3 discrete categories of activities in furtherance of the common purpose of the Opioid Marketing
4 Enterprise. The conduct of the members of the Opioid Marketing Enterprise in furtherance of
5 the Enterprise’s common purpose involved: (1) misrepresentations regarding the risk of
6 addiction and safe use of prescription opioids for long-term, chronic pain (described in detail
7 above); (2) efforts to criticize or undermine the 2016 CDC Guideline referenced above; and
8 (3) efforts to limit prescriber accountability.
9

10 299. In addition to disseminating misrepresentations about the risks and benefits
11 of opioids, members of the Opioid Marketing Enterprise also furthered its common purpose by
12 criticizing or undermining the CDC Guideline, which represented “an important step—and
13 perhaps the first major step from the federal government—toward limiting opioid prescriptions
14 for chronic pain.”¹²³
15

16 300. Several Front Groups, including the U.S. Pain Foundation and the American
17 Academy of Pain Medicine (AAPM), criticized the draft guidelines in 2015, arguing that the
18 “CDC slides presented on Wednesday were not transparent relative to process and failed to
19 disclose the names, affiliation, and conflicts of interest of the individuals who participated in
20 the construction of these guidelines.”¹²⁴
21

22 301. The AAPM criticized the prescribing guidelines in 2016, through its
23

24 ¹²³ Fueling an Epidemic, *supra* note 29, at 13.

25 ¹²⁴ Pat Anson, *Chronic Pain Groups Blast CDC for Opioid Guidelines*, Pain News Network, Sept. 22, 2015,
26 <https://www.painnewsnetwork.org/stories/2015/9/22/chronic-pain-groups-blast-cdc-for-opioid-guidelines> (last
27 accessed August 13, 2018).

1 immediate past president, stating “that the CDC guideline makes disproportionately strong
2 recommendations based upon a narrowly selected portion of the available clinical evidence.”¹²⁵

3 302. The Manufacturer Defendants alone could not have accomplished the
4 purpose of the Opioid Marketing Enterprise without the assistance of the Front Groups and
5 KOLs, who were perceived as “neutral” and more “scientific” than the Manufacturer
6 Defendants themselves. Without the work of the Front Groups and KOLs in spreading
7 misrepresentations about opioids, the Opioid Marketing Enterprise could not have achieved its
8 common purpose.
9

10 303. In short, the Manufacturer Defendants, the Front Groups, and the KOLs
11 were each willing participants in the Opioid Marketing Enterprise, had a common purpose and
12 interest in the object of the scheme, and functioned within a structure designed to effectuate the
13 Enterprise’s purpose.
14

15 304. Moreover, each of the Manufacturer Defendants exerted control over the
16 Opioid Marketing Enterprise and participated in the operation or management of its affairs,
17 directly or indirectly. From approximately the late 1990s to the present, that participation and
18 control was carried out in the following ways:
19

- 20 a. Creating and providing a body of deceptive, misleading, and unsupported
21 medical and popular literature, electronic and print advertisements, sales
22 and promotional training materials, and presentations about opioids that: (i)
23 understated the risks and overstated the benefits of long-term use; (ii)
24

25 ¹²⁵ Am. Acad. of Pain Medicine, CDC Guideline for Prescribing Opioids for Chronic Pain (Mar. 16, 2016),
26 <http://www.painmed.org/files/aapm-statement-cdc-guideline-for-prescribing-opioids-for-chronic-pain.pdf> (last
27 accessed August 3, 2018).

- 1 appeared to be the result of independent, objective research; and (iii) were
2 thus more likely to be relied upon by physicians, patients, and payors;
- 3 b. Selecting, cultivating, promoting, and paying Front Groups and KOLs
4 based on their willingness to communicate and distribute the Manufacturer
5 Defendants' messages about the use of opioids for chronic pain;
- 6 c. Providing substantial opportunities for Front Groups and KOLs to
7 participate in research studies on topics the Manufacturer Defendants
8 suggested or chose, with the predictable effect of ensuring that many
9 favorable studies appeared in the academic literature;
- 10 d. Paying KOLs to serve as consultants or on the Manufacturer Defendants'
11 advisory boards, or on the advisory boards and in leadership positions of
12 Front Groups, and to give talks, typically over meals or at conferences;
- 13 e. Paying significant amounts of money to the leaders and individuals
14 associated with Front Groups;
- 15 f. Donating to Front Groups to support talks that were typically presented
16 over meals or at conferences;
- 17 g. Disseminating false, misleading, imbalanced, and unsupported statements
18 regarding opioids through unbranded materials that appeared to be
19 independent publications from Front Groups;
- 20 h. Sponsoring programs put on by Front Groups that focused exclusively on
21 the use of opioids for chronic pain;
- 22 i. Developing and disseminating pro-opioid treatment guidelines with the help
23
24
25
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of the KOLs as authors and promoters, and Front Groups as publishers and supporters;

- j. Encouraging Front Groups to disseminate their pro-opioid messages to groups targeted by the Manufacturer Defendants, such as veterans and the elderly, and then funding that distribution;
- k. Concealing their relationship to and control of Front Groups and KOLs from the Plaintiff and the public at large; and
- l. Intending that Front Groups and KOLs would distribute, through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

305. In short, the Manufacturer Defendants controlled representations made about their prescription opioids, doled out funds to Pharmacy Benefit Managers and payments to KOLs, and ensured that representations made by KOLs, Front Groups, and the Manufacturer Defendants' sales detailers were consistent with the Manufacturer Defendants' messaging throughout the United States. The Front Groups and KOLs in the Opioid Marketing Enterprise were dependent on the Manufacturer Defendants for their financial structure and for career development and promotion opportunities.

306. The Front Groups also conducted and participated in the conduct of the Opioid Marketing Enterprise, directly or indirectly, in the following ways:

- a. The Front Groups promised to, and did, make representations regarding opioids and the Manufacturer Defendants' drugs that were consistent with the Manufacturer Defendants' messages;

- 1 b. The Front Groups distributed, through the U.S. Mail and interstate wire
2 facilities, promotional and other materials that claimed that opioids could be
3 safely used for chronic pain without addiction, and misrepresented the
4 benefits of using opioids for chronic pain;
5
6 c. The Front Groups echoed and amplified messages favorable to increased
7 opioid use—and ultimately, the financial interests of the Manufacturer
8 Defendants;
9
10 d. The Front Groups issued guidelines and policies minimizing the risk of
11 opioid addiction and promoting opioids for chronic pain;
12
13 e. The Front Groups strongly criticized the 2016 CDC Guideline, which had
14 recommended limits on opioid prescriptions for chronic pain; and
15
16 f. The Front Groups concealed their connections to the KOLs and the
17 Manufacturer Defendants.

18 307. The KOLs also participated in the conduct of the affairs of the Opioid
19 Marketing Enterprise, directly or indirectly, in the following ways:

- 20 a. The KOLs promised to, and did, make representations regarding opioids
21 and the Manufacturer Defendants' drugs that were consistent with the
22 Manufacturer Defendants' messages;
23
24 b. The KOLs distributed, through the U.S. Mail and interstate wire facilities,
25 promotional and other materials that claimed that opioids could be safely
26 used for chronic pain without addiction, and misrepresented the benefits of
27 using opioids for chronic pain;

- 1 c. The KOLs echoed and amplified messages favorable to increased opioid
2 use—and ultimately, the financial interests of the Manufacturer Defendants;
3 d. The KOLs issued guidelines and policies minimizing the risk of opioid
4 addiction and promoting opioids for chronic pain;
5 e. The KOLs strongly criticized the 2016 CDC Guideline, which had
6 recommended limits on opioid prescriptions for chronic pain; and
7 f. The KOLs concealed their connections to the Front Groups and the
8 Manufacturer Defendants, and their sponsorship by the Manufacturer
9 Defendants.
10

11 308. The scheme devised and implemented by the Manufacturer Defendants and
12 members of the Opioid Marketing Enterprise amounted to a common course of conduct
13 intended to increase the Manufacturer Defendants' sales from prescription opioids by
14 encouraging the prescribing and use of opioids for long-term, chronic pain. The scheme was a
15 continuing course of conduct, and many aspects of it continue to the present.
16

17 309. The Manufacturer Defendants, Front Groups and the KOLs thus worked
18 together to promote the goals of the Opioid Marketing Enterprise.
19

20 *c. The Pattern of Racketeering Activity*

21 310. The Manufacturer Defendants' scheme was perpetrated through multiple
22 acts of mail fraud and wire fraud that constituted a pattern of racketeering activity.
23

24 311. This pattern of racketeering activity involved thousands of separate
25 instances of the use of the U.S. Mail or interstate wire facilities, including misrepresentations,
26 concealments, and material omissions regarding the beneficial uses and non-addictive
27

1 qualities of prescription opioids for the long-term treatment of chronic, non-acute, and non-
2 cancer pain, with the goal of profiting from increased sales of the Manufacturer Defendants'
3 opioids.

4 312. Each of these fraudulent mailings and interstate wire transmissions
5 constitutes a separate act of racketeering activity, and collectively, these violations constitute a
6 pattern of racketeering activity.
7

8 313. The Manufacturer Defendants devised and knowingly carried out an illegal
9 scheme and artifice to defraud by means of materially false or fraudulent pretenses,
10 representations, promises, or omissions of material facts regarding the safe, non-addictive, and
11 effective use of opioids for long-term, chronic, non-acute, and non-cancer pain. The
12 Manufacturer Defendants and members of the Opioid Marketing Enterprise knew that these
13 representations violated the FDA-approved use of these drugs, and were not supported by
14 actual evidence. The Manufacturer Defendants used the U.S. Mail and interstate wire
15 facilities, intentionally and knowingly, with the specific intent to defraud and to advance their
16 illegal scheme.
17
18

19 314. The Manufacturer Defendants, the Front Groups, and the KOLs engaged in
20 a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity by
21 intentionally concealing the material risks and affirmatively misrepresenting the benefits of
22 using opioids for chronic pain to prescribers, regulators, the public, and the Plaintiff.
23

24 315. The Manufacturer Defendants' use of the U.S. Mail and interstate wire
25 facilities to perpetrate the fraudulent marketing of opioids involved thousands of
26 communications, publications, representations, statements, electronic transmissions, and
27

1 payments, including, *inter alia*:

- 2 a. Marketing materials about opioids and their risks and benefits, which
3 Manufacturer Defendants, Front Groups, and KOLs published and
4 transmitted to healthcare providers located across the country through the
5 Internet and television;
- 6 b. Written representations and telephone calls between the Manufacturer
7 Defendants and Front Groups regarding the misrepresentations, marketing
8 statements, and claims about opioids, including the non-addictive, safe use
9 of prescription opioids for chronic long-term pain generally;
- 10 c. Written representations and telephone calls between the Manufacturer
11 Defendants and KOLs regarding the misrepresentations, marketing
12 statements, and claims about opioids, including the non-addictive, safe use
13 of prescription opioids for chronic long-term pain generally;
- 14 d. E-mails, telephone calls, and written communications between the
15 Manufacturer Defendants and the Front Groups agreeing to or
16 implementing the scheme for the fraudulent marketing of opioids;
- 17 e. E-mails, telephone calls, and written communications between the
18 Manufacturer Defendants and the KOLs agreeing to or implementing the
19 scheme for the fraudulent marketing of opioids;
- 20 f. Communications between the Manufacturer Defendants, Front Groups, and
21 the media regarding publication, drafting of treatment guidelines, and the
22 dissemination of the same as part of the Opioid Marketing Enterprise;
- 23
24
25
26
27

- 1 g. Communications between the Manufacturer Defendants, KOLs, and the
2 media regarding publication, drafting of treatment guidelines, and the
3 dissemination of the same as part of the Opioid Marketing Enterprise;
4
5 h. Written and oral communications directed to state agencies, Federal and
6 state courts, and private insurers throughout the country that fraudulently
7 misrepresented the risks and benefits of using opioids for chronic pain; and
8
9 i. Receipts of increased profits—the wrongful proceeds of the scheme—sent
10 through the U.S. Mail and interstate wire facilities.

11 316. In addition to the above-referenced predicate acts, it was intended by and
12 foreseeable to the Manufacturer Defendants that the Front Groups and the KOLs would
13 distribute publications through the U.S. Mail and by interstate wire facilities, and, in those
14 publications, claim that the benefits of using opioids for chronic pain outweighed the risks of
15 doing so.

16 317. The Manufacturer Defendants, and each member of the Opioid Marketing
17 Enterprise, agreed, with knowledge and intent, to the overall objective of the Manufacturer
18 Defendants' fraudulent scheme and participated in the common course of conduct to commit
19 acts of fraud in marketing prescription opioids.
20

21 318. Indeed, for the Manufacturer Defendants' fraudulent scheme to work, each of
22 them had to agree to implement similar tactics regarding fraudulent marketing of prescription
23 opioids. This conclusion is supported by the fact that the Manufacturer Defendants each
24 financed, supported, and worked through the same KOLs and Front Groups, and often
25 collaborated on and mutually supported the same publications, presentations, and prescription
26
27

1 guidelines.

2 319. The Manufacturer Defendants’ predicate acts all had the purpose of creating
3 the opioid epidemic that substantially injured the Plaintiff’s business and property, while
4 simultaneously generating billion-dollar revenues and profits for the Manufacturer Defendants.
5 The predicate acts were committed or caused to be committed by the Manufacturer Defendants
6 through their participation in the Opioid Marketing Enterprise and in furtherance of its
7 fraudulent scheme.
8

9 2. The Opioid Supply Chain Enterprise

10 a. *The Common Purpose and Scheme of the Opioid Supply Chain Enterprise*
11

12 320. In addition to the Opioid Marketing Enterprise, there existed a second,
13 separate enterprise. For more than a decade, all Defendants worked together in an illicit
14 enterprise, engaging in illegal conduct with the common purpose and achievement of vastly
15 increasing their respective profits and revenues by exponentially expanding a market that the
16 law intended to restrict (the “Opioid Supply Chain Enterprise”).
17

18 321. As “registrants” under the CSA, Defendants are duty bound to identify and
19 report “orders of unusual size, orders deviating substantially from a normal pattern, and orders of
20 unusual frequency.” Critically, Defendants’ responsibilities do not end with the products they
21 manufacture or distribute—there is no such limitation in the law because their duties cut across
22 company lines. Thus, when Defendants obtain information about the sales and distribution of
23 other companies’ prescription opioid products (including both name-brand prescription opioids
24 and their generic equivalents), they were legally obligated to report that activity to the DEA. On
25 information and belief, the Defendants did in fact obtain such data through data mining
26
27

1 companies.

2 322. Defendants breached their duties under the CSA. Through the connections
3 they made as a result of their participation in the HDA, Defendants chose to flout the closed
4 system designed to protect citizens. Publicly, in 2008, they announced their formulation of
5 “Industry Compliance Guidelines: Reporting Suspicious Orders and Prevention of Diversion of
6 Controlled Substances.” But, privately, Defendants refused to act. Indeed, despite the issuance
7 of these Industry Compliance Guidelines (which recognize Defendants’ duties under the law),
8 none of them complied. This noncompliance is illustrated by the subsequent industry-wide
9 enforcement actions and consent orders issued after that time.
10

11 323. Further, John Gray, President and CEO of the HDA, said to Congress in
12 2014, it is “difficult to find the balance between proactive and anti-diversion efforts while not
13 inadvertently limiting access to appropriately prescribed and dispensed medications.”¹²⁶ Yet,
14 Defendants apparently all found the same profit-maximizing balance and intentionally remained
15 silent to ensure the largest possible financial return.
16

17 324. Defendants breached their duties under the CSA, and the breaches were part
18 of a common purpose and scheme. At all relevant times, Defendants operated as an association-
19 in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues, and profits by
20 fraudulently increasing the quotas set by the DEA that would allow them to benefit collectively
21 from a greater pool of prescription opioids. In support of this common purpose and fraudulent
22 scheme, Defendants jointly agreed to disregard their statutory duties to identify, investigate,
23
24

25 ¹²⁶ *Improving Predictability and Transparency in DEA and FDA Regulation: Hearing Before the Subcomm. on*
26 *Health of the H. Comm. on Energy and Commerce*, 113th Cong. (2014) (statement of John Gray, President and
27 CEO, HDA), <https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg90872/html/CHRG-113hhrg90872.htm>.

1 halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market.
2 Their collective silence in the face of their duties to speak constituted concealment of their
3 wrongdoing that effectively kept it hidden from the public and the Plaintiff until government
4 and media investigation revealed sufficient information to bring their wrongful conduct causing
5 the opioid epidemic to light, leading to the Complaint in this matter.
6

7 *b. The Conduct of the Opioid Supply Chain Enterprise*

8 325. At all relevant times, Defendants exerted control over, conducted, and/or
9 participated in the Opioid Supply Chain Enterprise by fraudulently claiming that they were
10 complying with their duties to identify, investigate, and report suspicious orders of opioids.
11

12 326. Defendants disseminated false and misleading statements to Federal and state
13 regulators claiming that:

- 14 a. the quotas for prescription opioids should be increased; and
15 b. they were complying with their obligations to: (i) maintain effective
16 controls against diversion of their prescription opioids; (ii) design and
17 operate a system to disclose suspicious orders of prescription opioids;
18 and (iii) notify the DEA of any suspicious orders or diversion of their
19 prescription opioids.
20

21 327. The CSA and the Code of Federal Regulations require Defendants to make
22 reports to the DEA of any suspicious orders identified through the design and operation of
23 their system to disclose suspicious orders. The failure to make reports as required by the CSA
24 and Code of Federal Regulations amounts to a criminal violation of the statute. It also
25 constitutes concealment of Defendants' wrongful fulfillment of suspicious orders.
26
27

1 328. Defendants knowingly and intentionally furnished false or fraudulent
2 information in their reports to the DEA about suspicious orders, and/or omitted material
3 information from reports, records, and other documents required to be filed with the DEA,
4 including the Manufacturer Defendants' applications for production quotas. Specifically,
5 Defendants were aware of suspicious orders of prescription opioids and the diversion of their
6 prescription opioids into the illicit market, and failed to report this information to the DEA in
7 their mandatory reports and their applications for production quotas.
8

9 *c. The Pattern of Racketeering Activity*
10

11 329. Defendants used, directed the use of, and/or caused to be used, thousands
12 of mail and interstate wire communications in service of their scheme through virtually
13 uniform misrepresentations, concealments, and material omissions regarding their compliance
14 with their mandatory reporting requirements and the actions necessary to carry out their
15 unlawful goal of selling prescription opioids without reporting suspicious orders or the
16 diversion of opioids into the illicit market.
17

18 330. Defendants devised and knowingly carried out a scheme and/or artifice to
19 defraud by means of materially false or fraudulent pretenses, representations, promises, or
20 omissions of material facts when there was a duty to disclose.
21

22 331. For the purpose of executing the illegal scheme, Defendants used the mail
23 and interstate wires intentionally and knowingly with the specific intent to defraud and
24 advance the illegal scheme. These repeated acts of mail fraud and wire fraud constituted a
25 pattern of racketeering activities.
26

27 332. Defendants' use of the mail and interstate wires included, but was not

1 limited to, the transmission, delivery, or shipment of the following by Defendants, or third
2 parties that foreseeably sent them as a result of Defendants' illegal scheme:

- 3 a. The prescription opioids themselves;
- 4 b. Documents and communications that supported and/or facilitated the
- 5 Defendants' request for higher aggregate production quotas, individual
- 6 production quotas, and procurement quotas;
- 7 c. Documents and communications that facilitated the manufacture, purchase,
- 8 and sale of prescription opioids;
- 9 d. Defendants' DEA registrations;
- 10 e. Documents and communications that supported and/or facilitated
- 11 Defendants' DEA registrations;
- 12 f. Defendants' records and reports that were required to be submitted to the
- 13 DEA pursuant to 21 U.S.C. § 827;
- 14 g. Documents and communications related to the Defendants' mandatory DEA
- 15 reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;
- 16 h. Documents intended to facilitate the manufacture and distribution of the
- 17 Defendants' prescription opioids, including bills of lading, invoices,
- 18 shipping records, reports, and correspondence;
- 19 i. Documents for processing and receiving payment for prescription opioids;
- 20 j. Payments from the Distributor Defendants to the Manufacturer Defendants;
- 21 k. Rebates and chargebacks from the Manufacturer Defendants to the
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Distributor Defendants;

- l. Payments to the Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;
- m. Deposits of proceeds from the Defendants' manufacture, distribution, and sale of prescription opioids; and
- n. Other documents and things, including electronic communications.

333. Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) by mail or by private or interstate carrier, shipments of prescription opioids and related documents affecting interstate commerce.

334. Defendants used the Internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the Defendants made misrepresentations about their compliance with Federal and state laws requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

335. At the same time, Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids, and their compliance with all Federal and state regulations regarding the identification and reporting of suspicious orders of prescription opioids.

336. The mail and wire transmissions described herein were made in furtherance

1 of Defendants' scheme and common course of conduct to deceive regulators, the public, and
2 the Plaintiff into believing that Defendants were complying with their Federal and state
3 obligations to identify and report suspicious orders of prescription opioids while Defendants
4 were knowingly allowing millions of doses of prescription opioids to be diverted into the
5 illicit drug market. Defendants' scheme and common course of conduct was to increase or
6 maintain high production quotas for their prescription opioids from which they could profit.
7

8 337. Many of the precise dates of the uses of the U.S. mail and interstate wire
9 facilities have been deliberately hidden by Defendants and cannot be alleged without access
10 to Defendants' books and records. However, the Plaintiff has described the types of and, in
11 some instances, occasions on which the predicate acts of mail and/or wire fraud occurred.
12 They include thousands of communications to perpetrate and maintain the scheme, including
13 the things and documents described in the preceding paragraphs.
14

15 338. The predicate acts constituted a variety of unlawful activities, each
16 conducted with the common purpose of obtaining significant monies and revenues from the
17 sale of their highly addictive and dangerous drugs. The predicate acts also had the same or
18 similar results, participants, victims, and methods of commission. The predicate acts were
19 related and not isolated events.
20

21 339. The predicate acts all had the purpose of creating the opioid epidemic that
22 substantially injured the Plaintiff's business and property, as well as the health and welfare of
23 the people served by the Plaintiff, while simultaneously generating billion-dollar revenue and
24 profits for Defendants. The predicate acts were committed or caused to be committed by
25 Defendants through their participation in the Opioid Supply Chain Enterprise and in
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1 furtherance of its fraudulent scheme.

2 340. As described above, Defendants were repeatedly warned, fined, and found
3 to be in violation of applicable laws and regulations, and yet they persisted. The sheer volume
4 of enforcement actions against Defendants supports this conclusion that Defendants operated
5 through a pattern and practice of willfully and intentionally omitting information from their
6 mandatory reports to the DEA as required by 21 C.F.R. § 1301.74.¹²⁷

7
8 341. By intentionally refusing to report and halt suspicious orders of their
9 prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of
10 conduct constituting a pattern of racketeering activity.

12 3. Effects of the Opioid Marketing Enterprise and the Opioid Supply Chain
13 Enterprise

14 342. The Plaintiff's injuries were proximately caused by Defendants' racketeering
15 activity. The racketeering activity was undertaken with the express purpose of influencing the
16 medical community of which the Plaintiff is a part, and/or of profiting from such influence, and
17 it directly caused the over-prescription, over-purchase, and over-consumption of name-brand
18 prescription opioids and their generic equivalents. But for Defendants' misstatements and
19 omissions and the schemes employed by the Opioid Marketing Enterprise and the Opioid
20 Supply Chain Enterprise, the Plaintiff would not be bearing the costs of the current opioid
21 epidemic.

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23 343. By reason of, and as a result of the conduct of each of the Defendants, and in
24 particular, their pattern of racketeering activity, the Plaintiff has been injured in their business
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1 and property in multiple ways, including, but not limited to, increased program and operational
2 costs.

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4 344. Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately
5 caused injuries and damages to the Plaintiff, and the Plaintiff is entitled to bring this action for
6 three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable
7 attorneys' fees pursuant to 18 U.S.C. § 1964(c).

8
9 V. CAUSES OF ACTION

10 COUNT 1: VIOLATION OF RICO
11 18 U.S.C. § 1961 *et seq.*
12 OPIOID MARKETING ENTERPRISE
(Against Manufacturing Defendants)

13 345. The Plaintiff incorporates by reference all preceding paragraphs of this
14 Complaint as if fully set forth herein and further alleges as follows.

15 346. At all relevant times, the Manufacturer Defendants were and are "persons"
16 under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or
17 beneficial interest in property."
18

19 347. The Opioid Marketing Enterprise was an association-in-fact enterprise
20 within the meaning of 18 U.S.C. § 1961(4) consisting of the Manufacturer Defendants, the
21 Front Groups, and the KOLs. The activities of this Enterprise affected interstate commerce.
22

23 348. At all relevant times, the Opioid Marketing Enterprise: (a) had an existence
24 separate and distinct from each member of the Opioid Marketing Enterprise; (b) was separate
25

26 ¹²⁷ Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement*
27 *Administration's Adjudication of Registrant Actions* 6 (2014), <https://oig.justice.gov/reports/2014/e1403.pdf>.

1 and distinct from the pattern of racketeering in which the Manufacturer Defendants engaged;
2 (c) was an ongoing and continuing organization consisting of individuals, persons, and legal
3 entities, including each of the Manufacturer Defendants; (d) was characterized by
4 interpersonal relationships between and among each member of the Opioid Marketing
5 Enterprise, including between the Manufacturer Defendants and each of the Front Groups and
6 KOLs; (e) had sufficient longevity for the Opioid Marketing Enterprise to pursue its purpose;
7 and (f) functioned as a continuing unit.
8

9 349. In particular, each of the Manufacturer Defendants, KOLs, and Front
10 Groups that made up the Opioid Marketing Enterprise had systematic links to, and personal
11 relationships with, each other through: (a) joint participation in lobbying groups; (b) trade
12 industry organizations; (c) contractual relationships; and (d) continuing coordination of
13 activities. These systematic links and personal relationships allowed members of the Opioid
14 Marketing Enterprise to act with a common purpose and to conduct and participate in the
15 conduct of the Opioid Marketing Enterprise. Specifically, each of the Manufacturer
16 Defendants coordinated their efforts through the same KOLs and Front Groups, based on their
17 agreement and understanding that the Front Groups and KOLs were industry-friendly and
18 would work together with the Manufacturer Defendants to advance the common purpose of
19 the Opioid Marketing Enterprise.
20
21

22 350. Each of the Manufacturer Defendants and the other members of the Opioid
23 Marketing Enterprise conducted and participated in the conduct of the Opioid Marketing
24 Enterprise by playing a role in furthering the Enterprise's common purpose of increasing
25 profits and sales through the knowing and intentional dissemination of false and misleading
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1 information about the safety and efficacy of long-term opioid use.

2 351. Specifically, the Manufacturer Defendants: (1) through the use of Front
3 Groups that appeared to be independent of the Manufacturer Defendants; (2) through the
4 dissemination of publications that supported the Manufacturer Defendants' scheme; (3)
5 through continuing medical education (CME) programs controlled and/or funded by the
6 Manufacturer Defendants; (4) by the hiring and deployment of so-called KOLs who were paid
7 by the Manufacturer Defendants to promote their message; and (5) through the "detailing"
8 activities of the Manufacturer Defendants' sales forces, conducted an association-in-fact
9 enterprise, and/or participated in the conduct of that enterprise through a pattern of illegal
10 activities (the predicate racketeering acts of mail and wire fraud) to carry out the common
11 purpose of the Opioid Marketing Enterprise.
12

13
14 352. The Opioid Marketing Enterprise sought to further this common purpose
15 through a fraudulent scheme to change prevailing views and prescribing habits within the
16 medical community, as well as public perception about the safety and efficacy of opioid use.
17 In so doing, each of the Manufacturer Defendants conducted and participated in the conduct
18 of the Opioid Marketing Enterprise by engaging in mail and wire fraud in violation of 18
19 U.S.C. § 1962(c).
20

21
22 353. Together with the Front Groups and KOLs, the Manufacturer Defendants
23 formed an association-in-fact enterprise, the Opioid Marketing Enterprise, for the purpose of
24 increasing unlawful profits and revenues from the continued prescription and use of name-
25 brand prescription opioids and their generic equivalents for long-term, chronic pain and
26 through creating widespread dependency on, and addiction to, opioids.
27

1 354. The Manufacturer Defendants each worked together to coordinate the
2 Opioid Marketing Enterprise's goals and conceal their role, and the Opioid Marketing
3 Enterprise's existence, from the medical community and the public by, among other things:
4 (a) funding, editing, and distributing publications that supported and advanced their false
5 messages; (b) funding KOLs to promote their false messages; (c) funding, editing, and
6 distributing CME programs to advance their false messages; and (d) tasking their own
7 employees to direct deceptive marketing materials and pitches directly at physicians and, in
8 particular, at physicians lacking the expertise of pain care specialists (that is, sales detailing).
9

10 355. Each of the Front Groups helped disguise the role of the Manufacturer
11 Defendants by purporting to be unbiased, independent patient-advocacy and professional
12 organizations in order to disseminate patient education materials—a body of biased and
13 unsupported scientific “literature,” and “treatment guidelines” that promoted the Manufacturer
14 Defendants' false messages.
15

16 356. Each of the KOLs was a physician chosen and paid by one or more of the
17 Manufacturer Defendants to influence prescribers' habits by promoting the Manufacturer
18 Defendants' false messages through, among other things, writing favorable journal articles and
19 delivering supportive CMEs as if they were independent medical professionals, thereby further
20 obscuring the Manufacturer Defendants' role in the Opioid Marketing Enterprise and the
21 Opioid Marketing Enterprise's existence.
22

23 357. The Manufacturer Defendants conducted and participated in the conduct of
24 the Opioid Marketing Enterprise through a pattern of racketeering activity within the meaning
25 of 18 U.S.C. § 1961(5) that employed the use of mail and interstate wire facilities, in violation
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1 of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud), to increase profits and revenue by
2 changing medical thinking, prescriber habits, and public perceptions in order to increase the
3 prescription and use of prescription opioids.

4
5 358. The Manufacturer Defendants, with knowledge and intent, agreed to the
6 overall objective of their fraudulent scheme and participated in the common course of conduct
7 to commit acts of fraud.

8
9 359. Indeed, for the Manufacturer Defendants' fraudulent scheme to work, each
10 of the Manufacturer Defendants had to agree to implement similar tactics.

11
12 360. The Manufacturer Defendants' predicate acts of racketeering activity (18
U.S.C. § 1961(1)) consisted of:

13 a. Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1341 by
14 sending or receiving, or by causing to be sent and/or received, materials via
15 U.S. mail or commercial interstate carriers for the purpose of executing the
16 unlawful scheme to design, manufacture, market, and sell the prescription
17 opioids by means of false pretenses, misrepresentations, false promises, and
18 omissions.
19

20 b. Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by
21 transmitting and/or receiving, or by causing to be transmitted and/or
22 received, materials by interstate wires for the purpose of executing the
23 unlawful scheme to design, manufacture, market, and sell the prescription
24 opioids by means of false pretenses, misrepresentations, false promises, and
25 omissions.
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1 361. Each of the Manufacturer Defendants not only violated the above laws but
2 also aided and abetted others in the violation of the above laws, thereby rendering the
3 Manufacturer Defendants indictable as principals.
4

5 362. As summarized herein, the Manufacturer Defendants used the mail and
6 interstate wires to send or receive thousands of communications, publications, representations,
7 statements, electronic transmissions, and payments to carry out the Opioid Marketing
8 Enterprise's fraudulent scheme.
9

10 363. Because the Manufacturer Defendants disguised their participation in the
11 Opioid Marketing Enterprise, and worked to keep even the Opioid Marketing Enterprise's
12 existence secret so as to give the false appearance that their false messages reflected the views
13 of independent third parties, many of the precise dates of the Opioid Marketing Enterprise's
14 uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail
15 and wire fraud) have been hidden and cannot be alleged without access to the books and
16 records maintained by the Manufacturer Defendants, Front Groups, and KOLs. Indeed, an
17 essential part of the successful operation of the Opioid Marketing Enterprise depended upon
18 secrecy. However, Plaintiff has described occasions on which the Manufacturer Defendants,
19 Front Groups, and KOLs disseminated misrepresentations and false statements to prescribers,
20 consumers, and regulators, and how those acts were in furtherance of the scheme.
21
22

23 364. The Manufacturer Defendants each committed, conspired to commit, and/or
24 aided and abetted in the commission of, at least two predicate acts of racketeering activity (i.e.,
25 violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of
26 racketeering activity that the Manufacturer Defendants committed, conspired to commit, and/or
27

1 aided and abetted in the commission of, were related to each other, posed a threat of continued
2 racketeering activity and/or constituted continuous racketeering activity, and therefore
3 constituted a “pattern of racketeering activity.” The racketeering activity was made possible by
4 the Manufacturer Defendants’ regular use of the facilities, services, distribution channels, and
5 employees of the Opioid Marketing Enterprise. The Manufacturer Defendants participated in
6 the scheme to defraud by using mail and interstate wires (including telephones and the
7 Internet) in interstate or foreign commerce.
8

9
10 365. As described herein, the Manufacturer Defendants engaged in a pattern of
11 related and continuous acts for years. Each instance of racketeering activity alleged herein was
12 related, had similar purposes, involved the same or similar participants and methods of
13 commission, and had similar results affecting similar victims, including consumers,
14 prescribers, regulators, and the Plaintiff.
15

16 366. The predicate acts constituted a variety of unlawful activities, each
17 conducted with the common purpose of obtaining significant money and revenue from the
18 marketing and sale of their highly addictive and dangerous drugs.
19

20 367. The Manufacturer Defendants, Front Groups, and KOLs intentionally
21 crafted their fraudulent scheme in accordance with the common purpose of the Opioid
22 Marketing Enterprise to ensure that their own profits—and the rewards of the scheme meted
23 out to the Front Groups and KOLs—remained high. In designing and implementing the
24 scheme, the Manufacturer Defendants understood and intended that those in the medical
25 community and the pharmaceutical distribution chain would rely on the integrity of the
26 pharmaceutical companies and ostensibly neutral third parties to provide objective and
27

1 scientific evidence regarding the Manufacturer Defendants' products.

2 368. The racketeering activities conducted by the Manufacturer Defendants, Front
3 Groups, and KOLs amounted to a common course of conduct, with a similar pattern and
4 purpose, intended to deceive the medical community, prescribers, consumers, and regulators.
5 The Manufacturer Defendants have engaged in the pattern of racketeering activity for the
6 purpose of conducting the ongoing affairs of the Opioid Marketing Enterprise.
7

8 369. The pattern of racketeering activity alleged herein is continuing as of the
9 date of this Complaint and, upon information and belief, will continue into the future unless
10 enjoined by this Court. The last racketeering incident occurred within five years of the
11 commission of a prior incident of racketeering.
12

13 370. The Manufacturer Defendants' violations of law and their pattern of
14 racketeering activity directly and proximately caused the Plaintiff's injury in their business and
15 property. The Manufacturer Defendants' pattern of racketeering activity was undertaken with
16 the express purpose of influencing the medical community of which the Plaintiff is a part,
17 and/or of profiting from such influence, and it logically, substantially, and foreseeably caused
18 an opioid epidemic. The Plaintiff's injuries in responding to that epidemic were not
19 unexpected, unforeseen, or independent. Rather, as the Plaintiff alleges, the Manufacturer
20 Defendants knew that the opioids were unsuited to treatment of long-term, chronic, non-acute,
21 and non-cancer pain, or for any other use not approved by the FDA, and knew that opioids
22 were highly addictive and subject to abuse. They further knew that widespread use of
23 prescription opioids could lead to widespread opioid addiction and therefore misuse.
24 Nevertheless, the Manufacturer Defendants engaged in a scheme that utilized the mail and
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1 interstate wires in order to carry out the Opioid Marketing Enterprise's fraudulent scheme,
2 thereby increasing the market for and sales of their opioid products.

3
4 371. Specifically, the Manufacturer Defendants' creation of, and then
5 participation in, the Opioid Marketing Enterprise through a pattern of racketeering activities to
6 carry out their fraudulent scheme has injured the Plaintiff in the form of substantial losses of
7 money and property that logically, directly, and foreseeably arose from the opioid epidemic.
8 The Plaintiff's injuries, as alleged throughout this Complaint, are hereby expressly
9 incorporated herein by reference.
10

11 372. The Plaintiff is the most directly harmed, and there is no other plaintiff
12 better suited to seek a remedy for the economic harms at issue here. Among other things, no
13 other party is responsible for the unreimbursed costs of services provided to the Plaintiff's
14 beneficiaries and other qualifying individuals, or for the overhead and programmatic costs
15 described in this Complaint.
16

17 COUNT 2: VIOLATION OF RICO
18 18 U.S.C. § 1961 *et seq.*
19 OPIOID SUPPLY CHAIN ENTERPRISE
(Against All Defendants)

20 373. The Plaintiff incorporates by reference all preceding paragraphs of this
21 Complaint as if fully set forth herein and further alleges as follows.

22 374. At all relevant times, the Defendants were and are "persons" under 18 U.S.C.
23 § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial
24 interest in property."
25

26 375. The Defendants together formed an association-in-fact enterprise, the Opioid
27

1 Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the
2 increased volume of opioid sales in the United States, including but not limited to creating a
3 market for non-medical use of opioids of epidemic proportions. The Opioid Supply Chain
4 Enterprise was an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4)
5 consisting of the Defendants. The activities of the Opioid Supply Chain Enterprise affected
6 interstate commerce.
7

8 376. At all relevant times, the Opioid Supply Chain Enterprise: (a) had an
9 existence separate and distinct from each member of the Opioid Supply Chain Enterprise; (b)
10 was separate and distinct from the pattern of racketeering in which the Defendants engaged; (c)
11 was an ongoing and continuing organization consisting of legal entities, including each of the
12 Defendants; (d) was characterized by interpersonal relationships between and among each
13 member of the Opioid Supply Chain Enterprise, i.e., the Defendants; (e) had sufficient
14 longevity for the Opioid Supply Chain Enterprise to pursue its purpose; and (f) functioned as a
15 continuing unit. Each member of the Opioid Supply Chain Enterprise participated in the
16 conduct of the Enterprise through a pattern of racketeering activity, and shared in the
17 astounding growth of profits supplied by fraudulently inflating opioid quotas and the resulting
18 sales.
19
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21 377. Many of the Defendants are members, participants, and/or sponsors of the
22 HDA/HDMA, and have been since at least 2006, and utilized the HDA/HDMA to form the
23 systematic links and interpersonal relationships of the Opioid Supply Chain Enterprise and to
24 assist the Defendants in engaging in the pattern of racketeering activity that gives rise to this
25 Count.
26
27

1 378. The Defendants conducted and participated in the conduct of the Opioid
2 Supply Chain Enterprise through a pattern of racketeering activity within the meaning of 18
3 U.S.C. § 1961(5).

4 379. The pattern of racketeering activity of the Opioid Supply Chain Enterprise
5 included the use of mail and interstate wire facilities, in furtherance of a scheme to defraud
6 Federal and state regulators, the American public, and the Plaintiff in violation of 18 U.S.C. §
7 1341 (mail fraud) and § 1343 (wire fraud).

8 380. The pattern of racketeering activity of the Opioid Supply Chain Enterprise
9 also included the felonious manufacture, importation, receiving, concealment, buying, selling,
10 or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of
11 the Controlled Substance Act), punishable under the laws of the United States.

12 381. Specifically, 21 U.S.C. § 843(a)(4) makes it unlawful for any person
13 knowingly or intentionally to furnish false or fraudulent information in, or omit any material
14 information from, any application, report, record, or other document required to be made, kept,
15 or filed under that subchapter. A violation of 21 U.S.C. § 843(a)(4) is punishable by up to four
16 years in jail, making it a felony. 21 U.S.C. § 843(d)(1). The Defendants violated 21 U.S.C. §
17 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material
18 information from, reports, records, and other documents required to be made, kept, and filed
19 under the relevant subchapter of Title 21 of the United States Code.

20 382. The Defendants, with knowledge and intent, agreed to the overall objective
21 of their fraudulent scheme and participated in the common course of conduct to commit acts of
22 fraud.
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1 383. Indeed, for the Defendants' fraudulent scheme to work, each of the
2 Defendants had to agree to implement similar tactics.

3 384. In sum, the Defendants' predicate acts of racketeering activity (18 U.S.C.
4 § 1961(1)) consisted of:
5

- 6 a. Mail Fraud: The Defendants violated 18 U.S.C. § 1341 by sending or
7 receiving, or by causing to be sent and/or received, materials via U.S. mail
8 or commercial interstate carriers for the purpose of executing the unlawful
9 scheme to design, manufacture, market, and sell the prescription opioids by
10 means of false pretenses, misrepresentations, false promises, and omissions.
11
- 12 b. Wire Fraud: The Defendants violated 18 U.S.C. § 1343 by transmitting
13 and/or receiving, or by causing to be transmitted and/or received, materials
14 by interstate wire for the purpose of executing the unlawful scheme to
15 design, manufacture, market, and sell the prescription opioids by means of
16 false pretenses, misrepresentations, false promises, and omissions.
17
- 18 c. Controlled Substance Violations: The Defendants who are Distributor
19 Defendants violated 21 U.S.C. § 843 by knowingly or intentionally
20 furnishing false or fraudulent information in, and/or omitting material
21 information from, documents filed with the DEA.

22 385. Each of the Defendants not only violated the above laws but aided and
23 abetted others in the violation of the above laws, thereby rendering Defendants indictable as
24 principals.
25

26 386. Many of the precise dates of the Defendants' criminal actions at issue here
27

1 have been hidden by Defendants and cannot be alleged without access to Defendants' books
2 and records. Indeed, an essential part of the successful operation of the Opioid Supply Chain
3 Enterprise alleged herein depended upon secrecy.

4 387. The Defendants hid from the general public and suppressed and/or ignored
5 warnings from third parties, whistleblowers, and governmental entities about the reality of the
6 suspicious orders that the Defendants were filling on a daily basis—leading to the diversion of
7 hundreds of millions of doses of name-brand and generic prescription opioids into the illicit
8 market.

9 388. The Defendants committed, conspired to commit, and/or aided and abetted
10 in the commission of, at least two predicate acts of racketeering activity within the past ten
11 years.

12 389. The multiple acts of racketeering activity that the Defendants committed,
13 conspired to commit, and/or aided and abetted in the commission of, were related to each
14 other, posed a threat of continued racketeering activity and/or constituted continuous
15 racketeering activity, and therefore constituted a “pattern of racketeering activity.” The
16 racketeering activity was made possible by the Defendants’ regular use of the facilities,
17 services, distribution channels, and employees of the Opioid Supply Chain Enterprise.

18 390. As described herein, the Defendants engaged in a pattern of related and
19 continuous predicate acts for years. Each instance of racketeering activity alleged herein was
20 related, had similar purposes, involved the same or similar participants and methods of
21 commission, and had similar results affecting similar victims, including consumers,
22 prescribers, regulators, and the Plaintiff. The predicate acts consisted of a variety of unlawful
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1 activities, each conducted with the common purpose of obtaining significant monies and
2 revenues from the distribution and sale of their highly addictive and dangerous drugs. The
3 predicate acts were not isolated or sporadic events.

4 391. The predicate acts all had the purpose of creating the opioid epidemic that
5 substantially injured the Plaintiff's business and property, as well as the health and welfare of
6 the people served by the Plaintiff, while simultaneously generating billion-dollar revenue and
7 profits for the Defendants. The predicate acts were committed or caused to be committed by
8 the Defendants through their participation in the Opioid Supply Chain Enterprise and in
9 furtherance of its fraudulent scheme.

10 392. The pattern of racketeering activity alleged herein is continuing as of the
11 date of this Complaint and, upon information and belief, will continue into the future unless
12 enjoined by this Court.

13 393. By intentionally refusing to report and halt suspicious orders of their
14 prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of
15 conduct constituting a pattern of racketeering activity.

16 394. It was foreseeable to the Defendants that the Plaintiff would be harmed
17 when they refused to report and halt suspicious orders, because their violation of the duties
18 imposed by the CSA and Code of Federal Regulations allowed the widespread diversion of
19 name-brand and generic prescription opioids out of appropriate medical channels and into the
20 illicit drug market—causing the opioid epidemic that the CSA intended to prevent.

21 395. The last racketeering incident occurred within five years of the commission
22 of a prior incident of racketeering.

1 396. The Defendants' violations of law and their pattern of racketeering activity
2 directly and proximately caused the Plaintiff's injury in their business and property. The
3 Defendants' pattern of racketeering activity, including their refusal to identify, report, and halt
4 suspicious orders of controlled substances, logically, substantially, and foreseeably caused an
5 opioid epidemic. The Plaintiff was injured and continues to be injured by the Defendants'
6 pattern of racketeering activity and the opioid epidemic that it created.
7

8 397. Defendants knew that the opioids they manufactured and supplied were
9 unsuited to treatment of long-term, chronic, non-acute, and non-cancer pain, or for any other
10 use not approved by the FDA, and knew that opioids were highly addictive and subject to
11 abuse. Nevertheless, in order to increase sales of their opioid products, the Defendants engaged
12 in a scheme of deception by refusing to identify or report suspicious orders of prescription
13 opioids that they knew were actually being diverted into the market of non-medical use. They
14 did so by utilizing the mail and interstate wires as part of their fraud.
15

16 398. The Defendants' predicate acts and pattern of racketeering activity were a
17 proximate cause of the opioid epidemic that has injured the Plaintiff in the form of substantial
18 losses of money and property that logically, directly, and foreseeably arise from the opioid
19 epidemic brought on by the Defendants' acts.
20

21 399. Specifically, the predicate acts and pattern of racketeering activity
22 proximately caused the Plaintiff's injuries, as alleged throughout this Complaint, and such
23 allegations are expressly incorporated herein by reference.
24

25 400. The Plaintiff is most directly harmed, and there is no other plaintiff better
26 suited to seek a remedy for the economic harms at issue here. Among other things, no other
27

1 party is responsible for the unreimbursed costs of services provided to the Plaintiff's
2 beneficiaries and other qualifying individuals, or for the overhead and programmatic costs
3 described in this Complaint.

4
5 **COUNT 3: PUBLIC NUISANCE**
6 **(Against All Defendants)**

7 401. The Plaintiff incorporates by reference all preceding paragraphs of this
8 Complaint as if fully set forth herein and further alleges as follows.

9 402. Public nuisance is an unreasonable interference with a right common to the
10 general public, such as a condition dangerous to health, offensive to community moral
11 standards, or unlawfully obstructing the public in the free use of public property.

12 403. Defendants' conduct, as described in the Complaint, involves a significant
13 interference with the public health, the public safety, the public peace, the public comfort or the
14 public convenience, and unreasonably interferes with a public right.

15 404. Manufacturer Defendants knew and should have known that their promotion
16 of opioids was false and misleading and that their deceptive marketing practices and other
17 unlawful, unfair, and fraudulent actions would create or assist in the creation of a public
18 nuisance.

19 405. Distributor Defendants likewise knew and should have known that their
20 failure to use reasonable care or comply with statutory requirements in the distribution of
21 prescription opioids, including the failure to implement effective controls and procedures in
22 their supply chains to guard against theft, diversion, and misuse of controlled substances and to
23 adequately design and implement a system to detect, halt, and report suspicious orders, would
24 create or assist in the creation of a public nuisance.
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1 406. By these actions, all Defendants have created or assisted in the creation of a
2 condition that is injurious to public health and safety and offensive to community moral
3 standards throughout the State of Alaska and within the geographic areas and patient population
4 served by the Plaintiff. That nuisance is the over-saturation of opioids, as well as the adverse
5 social, economic, and human health outcomes associated with widespread illegal opioid use,
6 including injury, addiction, and death.

7
8 407. The Defendants' actions in creating or assisting in the creation of this
9 nuisance were a legal cause of significant harm to the Plaintiff that is different in kind, and not
10 just degree, from the harm to the general public. The Plaintiff is responsible for the provision of
11 health care services to Alaska Natives, American Indians, and other eligible individuals in the
12 geographic areas they serve pursuant to agreements with the federal government under the
13 ISDEAA. The provision of such services is in furtherance of the unique federal trust
14 responsibility to Alaska Natives and American Indians. The resources available to the Plaintiff
15 to carry out this responsibility has been and is being unreasonably consumed, as described
16 above, in efforts to address the opioid epidemic, costing the Plaintiff considerable sums of
17 money; diverting available resources needed in other health care areas that are part of the
18 federal trust responsibility; and frustrating the Plaintiff's ability to meet its responsibilities and
19 carry out its mission under federal laws and agreements.

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21
22 408. The public nuisance is substantial and unreasonable. Defendants' actions
23 caused and continue to cause the public health epidemic and state of emergency described in
24 this Complaint, and that harm outweighs any offsetting benefit.

25
26 409. Defendants' actions were, at the very least, a substantial factor in opioids
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1 becoming widely available and widely used, in deceiving prescribers and patients about the
2 risks and benefits of opioids for the treatment of chronic pain, in the diversion of prescription
3 opioids for illicit purposes, and in the public health crisis that followed and has reached a state
4 of emergency.

5
6 410. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and
7 maintained by Defendants can be abated, and further recurrence of such harm can be abated.

8 411. The Plaintiff has been, and continues to be, injured by Defendants' actions in
9 creating a public nuisance.

10 412. Defendants should be required to pay the expenses the Plaintiff has incurred
11 or will incur in the future to fully abate the nuisance.

12
13 COUNT 4: NEGLIGENCE AND GROSS NEGLIGENCE
14 (Against All Defendants)

15 413. The Plaintiff incorporates by reference all preceding paragraphs of this
16 Complaint as if fully set forth herein and further alleges as follows.

17 414. Each Defendant owed and owes a non-delegable duty of care to the Plaintiff,
18 including, but not limited to, the duty to exercise due care in the advertising, marketing,
19 promotion, sale and distribution of dangerous opioid drugs; the duty not to make false,
20 misleading, or deceptive statements about opioids; and the duty to take reasonable steps to
21 prevent diversion, misuse, and abuse of prescription opioid drugs.

22 415. Defendants knew, or should have known, that they breached the duties
23 described above.

24 416. As set forth above, Defendants' negligent acts include falsely claiming that
25 the risk of opioid addiction was low; falsely instructing doctors and patients that prescribing
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1 more opioids was appropriate when patients presented symptoms of addiction; falsely claiming
2 that risk-mitigation strategies could safely address concerns about addiction; falsely claiming
3 that doctors and patients could increase opioid usage indefinitely without added risk;
4 deceptively marketing that purported abuse-deterrent technology could curb misuse and
5 addiction; falsely claiming that long-term opioid use could actually restore function and
6 improve a patient's quality of life; and consciously oversupplying the market for opioids in the
7 State of Alaska and the geographic area served by the Plaintiff. These actions were intended to,
8 and foreseeably did, inflate the market for opioids in Alaska and the geographic areas served
9 by the Plaintiff.
10

11
12 417. In addition, each Defendant knew or should have known, and/or recklessly
13 disregarded, that the opioids they manufactured, promoted, and/or distributed were being used
14 for unintended uses.

15 418. For instance, Defendants failed to exercise slight care to the Plaintiff by,
16 inter alia, failing to take appropriate action to stop opioids from being used for unintended
17 purposes, including the failure to report suspicious orders or refuse to fill them or otherwise to
18 provide effective controls and procedures to guard against theft and diversion. Furthermore,
19 despite each Defendant's actual or constructive knowledge of the wide proliferation and
20 dissemination of opioids in Alaska and the geographic areas served by the Plaintiff, Defendants
21 took no action to prevent the abuse and diversion of their pharmaceutical drugs.
22

23 419. Defendants knew or should have known, and/or recklessly disregarded, the
24 fact that the Plaintiff, as a health care provider, would be forced to incur costs and divert
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resources to treat opioid-affected patients and otherwise respond to the opioid epidemic brought about by Defendants' actions, including the cost of unreimbursed care.

420. But for Defendants' actions, opioid use would not have become so widespread, including within the geographic area and among the population served by the Plaintiff, and the enormous public health hazard of prescription opioid and heroin overuse, abuse, and addiction that now exists would have been averted.

421. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, the Plaintiff has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial.

COUNT 5: NEGLIGENCE PER SE
(Against All Defendants)

422. The Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

423. All Defendants were obligated to prevent the diversion of prescription opioids under the CSA and its implementing regulations.

424. The CSA and its implementing regulations were enacted to promote safety and to prevent exactly the type of harm that occurred as a result of Defendants' failures.

425. For negligence *per se*, the court may adopt as the standard of conduct the requirements of a legislative enactment or administrative regulation when the purpose of that legislation or regulation is found to be exclusively or in part: (a) to protect a class of persons which includes the one whose interest is invaded; (b) to protect the particular interest which is being invaded; (c) to protect that interest against the kind of harm which has resulted; and (d) to protect that interest against the particular hazard from which the harm results. *Estate of*

1 *Logusak ex rel. Logusak v. City of Togiak*, 185 P.3d 103, 107 (Alaska 2008). As long as the
2 legislative enactment is “not too obscure, outdated or irrational to operate as a standard of
3 reasonable care, the court will instruct the jury that violation of a statute establishes negligence
4 *per se*.” *Sinclair v. Okata*, 874 F. Supp. 1051, 1062 (D. Alaska 1994).

5
6 426. The Plaintiff belongs to the class of persons that the statute was designed to
7 protect, because the CSA was designed to protect the public from the harms that may be caused
8 by the diversion of dangerous drugs from legal to illegal channels and uses. Plaintiff has
9 suffered harms, as detailed above, of the sort contemplated by the CSA because of Defendants’
10 failures, among other things, to prevent the diversion of opioids.

11
12 427. Defendants’ conduct was negligent *per se* in that Defendants failed to
13 perform their statutory and regulatory obligations under the CSA.

14 428. Defendants’ breaches of their duty of care foreseeably and proximately
15 caused damage to the Plaintiff, as alleged above.

16 429. The Plaintiff is entitled to damages from Defendants in an amount to be
17 determined in this litigation.

18
19 COUNT 6: UNJUST ENRICHMENT
20 (Against All Defendants)

21 430. The Plaintiff incorporates by reference all preceding paragraphs of this
22 Complaint as if fully set forth herein and further alleges as follows.

23 431. Defendants have unjustly retained a benefit to the Plaintiff’s detriment, and
24 Defendants’ retention of that benefit violates the fundamental principles of justice, equity, and
25 good conscience.

26 432. The Plaintiff has expended substantial amounts of money to address,
27

1 remedy, and/or mitigate the harms caused by Defendants' conduct, including providing
2 unreimbursed health care and otherwise having to manage the crisis of opioid addiction,
3 overdose, injury, and death that Defendants helped create.

4 433. The expenditures by the Plaintiff in providing treatment services to people
5 who use or are affected by opioids have added to Defendants' wealth. These expenditures
6 should have been borne by the Defendants, and instead the Plaintiff has helped to sustain
7 Defendants' business.

8 434. The Plaintiff has conferred a benefit upon Defendants, by paying for what
9 may be called Defendants' externalities—the costs of the harm caused by Defendants'
10 negligent distribution and sales practices. This includes providing treatment services to people
11 who use or are affected by opioids. It includes necessary training and retraining to correct the
12 misinformation that patients, doctors and the general public, including members served by the
13 Plaintiff, have received.

14 435. Defendants were aware they were receiving this obvious benefit.

15 436. Meanwhile, Defendants made substantial profits while fueling the opioid
16 epidemic in Alaska and the geographic area and patient population served by the Plaintiff.

17 437. Defendants continue to receive considerable profits from the distribution of
18 controlled substances in Alaska and the geographic area served by the Plaintiff.

19 438. It would be inequitable for Defendants to retain the full benefit or financial
20 advantage of their wrongdoing without paying for the externalities necessarily borne by the
21 Plaintiff, and Defendants should be disgorged of money retained by reason of their deceptive
22 and illegal acts.

1 439. Because the Defendants were unjustly enriched, the Plaintiff is entitled to
2 recover from Defendants' prescription opioid profits the amounts the Plaintiff has spent and
3 will have to spend in the future to address the effects of Defendants' actions.

4
5 COUNT 7: CIVIL CONSPIRACY
6 (Against All Defendants)

7 440. The Plaintiff incorporates by reference all preceding paragraphs of this
8 Complaint as if fully set forth herein and further alleges as follows.

9 441. A civil conspiracy claim requires (1) two or more persons (or entities); (2)
10 an object to be accomplished; (3) a meeting of minds on the object or course of action; (4) one
11 or more unlawful, overt acts; and (5) damages as the proximate result. *Hensel v. Allstate Ins.*
12 *Co.*, 2007 WL 5613094; *see* 16 Am.Jur. 2d Conspiracy § 51.

13 442. The Defendants engaged in a civil conspiracy by agreeing to participate in a
14 campaign to accomplish the goals of flooding the market with false and misleading information
15 about the safety of prescription opioid use for the treatment of chronic pain, evading controls on
16 opioid diversion, and increasing opioid quotas.

17
18 443. The Defendants did so in an effort to profit off the increased sales of
19 prescription opioids.

20 444. Each Defendant took one or more unlawful, overt act, including making false
21 or misleading statements directly and through third parties to further the objectives of their
22 conspiracy. These overt acts, as further described above, include but are not limited to acts of
23 mail fraud and wire fraud in furtherance of the Enterprises, and violations of the CSA.

24 445. The Plaintiff was directly and proximately harmed by the Defendants' civil
25 conspiracy, as alleged in this Complaint, in an amount to be determined in this litigation.
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COUNT 8: FRAUD AND NEGLIGENT MISREPRESENTATION
(Against Manufacturer Defendants)

446. The Plaintiff incorporates by reference all preceding paragraphs of this Complaint as if fully set forth herein and further alleges as follows.

447. Manufacturer Defendants made fraudulent and/or negligent misrepresentations and omissions of material fact about the use of opioids as part of a widespread misinformation campaign, as more fully described in Paragraphs 139 to 182 and throughout Complaint, which are specifically incorporated here by reference. These misrepresentations and omissions include:

- a. Defendant Purdue, with assistance from Defendant Abbott from 1996 through 2002, made and/or disseminated deceptive statements, including, but not limited to, the following: (a) advertising that opioids improved long-term functioning and were suitable for the treatment of chronic non-cancer pain; (b) promoting the concept of pseudo-addiction; (c) brochures concerning indicators of possible opioid abuse; (d) suitability of opioids for high-risk patients; (e) publications presenting an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs; (f) concealment of funding of pro-opioid KOL doctors regarding treatment for chronic non-cancer pain; (g) downplaying of the risks of opioid addiction; (h) CMEs promoting the use of opioids to treat chronic non-cancer pain; (i) promotion of misleading scientific studies regarding the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain; (j) misuse and promotion of data to mask the true safety and efficacy of opioids for the

1 long-term treatment of chronic non-cancer pain, including rates of abuse and
2 addiction and the lack of validation for long-term efficacy; (k) misleading
3 statements in education materials for doctors and staff across the United
4 States and in Alaska under the guise of educating them on new pain
5 standards; (l) in-person detailing; and (m) withholding from law
6 enforcement the names of prescribers Purdue believed to be facilitating the
7 diversion of its products, while simultaneously marketing opioids to these
8 doctors by disseminating patient and prescriber education materials and
9 advertisements and CMEs.
10

- 11 b. Defendant Endo made and/or disseminated deceptive statements, including,
12 but not limited to, the following: (a) false patient education materials; (b)
13 advertising the ability of opioids to improve function long-term and the
14 efficacy of opioids long-term for the treatment of chronic non-cancer pain;
15 (c) promoting chronic opioid therapy as safe and effective for long term use
16 for high- risk patients; (d) creating and disseminating advertisements that
17 falsely and inaccurately conveyed the impression that Endo's opioids would
18 provide a reduction in oral, intranasal, or intravenous abuse; (e) concealing
19 the true risk of addiction and promoting the misleading concept of pseudo-
20 addiction; (f) promoting an unbalanced treatment of the long-term and dose-
21 dependent risks of opioids versus NSAIDs; (g) secretly funding pro-opioid
22 KOLs, who made deceptive statements concerning the use of opioids to treat
23 chronic non-cancer pain; (h) funding pro-opioid pain organizations
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1 responsible for egregious misrepresentations concerning the use of opioids
2 to treat chronic non-cancer pain; (i) downplaying the risks of opioid
3 addiction in the elderly; (j) CMEs containing deceptive statements
4 concerning the use of opioids to treat chronic non-cancer pain; (k)
5 misleading scientific studies concluding opioids are safe and effective for
6 the long-term treatment of chronic non-cancer pain and quality of life, while
7 concealing contrary data; (l) funding and promoting pro-opioid KOLs
8 concerning the use of opioids to treat chronic non-cancer pain, including the
9 concept of pseudo-addiction; (m) manipulation of data regarding safety and
10 efficacy of opioids for the long-term treatment of chronic non-cancer pain,
11 including known rates of abuse and addiction and the lack of validation for
12 long-term efficacy; and (n) in-person detailing.

- 15 c. Defendant Janssen made and/or disseminated deceptive statements,
16 including, but not limited to, the following: (a) patient education materials
17 containing deceptive statements regarding the suitability, benefits, and
18 efficacy of opioids; (b) stating that opioids were safe and effective for the
19 long-term treatment of chronic non-cancer pain; (c) stating that opioids
20 improve quality of life, while concealing contrary data; (d) concealing the
21 true risk of addiction; (e) promoting the deceptive concept of pseudo-
22 addiction; (f) promoting opioids for the treatment of conditions for which
23 Janssen knew, due to the scientific studies it conducted, that opioids were
24 not efficacious, and concealing this information; (g) presenting to the public
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1 and doctors an unbalanced treatment of the long-term and dose-dependent
2 risks of opioids versus NSAIDs; (h) funding pro-opioid KOLs, who made
3 deceptive statements concerning the use of opioids to treat chronic non-
4 cancer pain; (i) funding pro-opioid pain organizations that made deceptive
5 statements, including in patient education materials, concerning the use of
6 opioids to treat chronic non-cancer pain; (j) using CMEs to promote false
7 statements concerning the use of opioids to treat chronic non-cancer pain;
8 and (k) in-person detailing.

10 d. Defendant Cephalon made and/or disseminated untrue, false, and deceptive
11 statements including, but not limited to, the following: (a) minimizing the
12 risk of opioid addiction; (b) promoting the deceptive concept of pseudo-
13 addiction; (c) advocating the use of opioids for chronic non-cancer pain; (d)
14 funding misleading CMEs, KOL doctors, and pain organizations; (e)
15 minimizing the addictiveness of Cephalon's potent rapid-onset opioids; and
16 (f) promoting the suitability of Cephalon's rapid-onset opioids to general
17 practitioners, neurologists, sports medicine specialists, and workers'
18 compensation programs.

21 e. Defendant Insys made and/or disseminated untrue, false, and deceptive
22 statements including, but not limited to, the following: (a) minimizing the
23 risk of opioid addiction; (b) promoting the deceptive concept of pseudo-
24 addiction; and (c) advocating the use of opioids for chronic non-cancer pain
25 by funding pain organizations and KOLs. Further, Insys, through its sales
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1 representatives and other marketing efforts, deceptively promoted Subsys as
2 safe and appropriate for uses such as neck and back pain, without disclosing
3 the lack of approval or evidence for such uses, and misrepresented the
4 appropriateness of Subsys for treatment of those conditions. Insys further
5 implemented a kickback scheme wherein it paid prescribers for fake
6 speakers programs in exchange for prescribing Subsys.
7

- 8 f. Defendants Actavis and Mallinckrodt made and/or disseminated deceptive
9 statements, including, but not limited to, the following: (a) promotion of use
10 of opioids to treat chronic non-cancer pain to prescribers throughout the
11 country and in Alaska through in-person detailing; (b) advertising that
12 opioids were safe and effective for the long-term treatment of chronic non-
13 cancer pain and that opioids improved quality of life; and (c) advertising
14 that concealed the risk of addiction in the long-term treatment of chronic
15 non-cancer pain.
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18 448. Manufacturer Defendants knew or reasonably should have known that their
19 statements were untrue, and they failed to correct these misrepresentations and omissions. The
20 misrepresentations and omissions were recklessly or negligently made.

21 449. Manufacturer Defendants made those misrepresentations and omissions in
22 an intentional effort to deceive health care providers, physicians, and the general public
23 throughout the United States and Alaska. Manufacturer Defendants intended that healthcare
24 providers, physicians, and the public would rely on these statements and omissions.
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1 450. Manufacturer Defendants knew or reasonably should have known that the
2 statements and omissions would and did, in fact, deceive physicians, health care providers,
3 their patients, and the public throughout the United States, including Alaska, including
4 physicians and other health care providers serving the Plaintiff and its patients. These
5 deceptive acts had the intent and effect of inducing over-prescription, over-reliance, and over-
6 use of prescription opioids.
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8 451. As a direct and proximate result of Manufacturer Defendants'
9 misrepresentations and material omissions, the Plaintiff has suffered and continues to suffer
10 damages in an amount to be determined in this litigation.
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12 COUNT 9: VIOLATIONS OF THE ALASKA UNFAIR TRADE PRACTICES
13 AND CONSUMER PROTECTION ACT
14 AS 45.50.471, *et seq.*
15 (Against All Defendants)

16 452. The Plaintiff incorporates by reference all preceding paragraphs of this
17 Complaint as if fully set forth herein and further alleges as follows.

18 453. The Alaska Unfair Trade Practices and Consumer Protection Act is codified
19 at AS 45.50.471 *et seq.* (UTPA).

20 454. The UTPA prohibits unfair methods of competition and unfair or deceptive
21 acts or practices in the conduct of trade or commerce.

22 455. All Defendants are engaged in trade or commerce in the State of Alaska.

23 456. Defendants violated the UTPA by engaging in deceptive trade practices
24 through the marketing, advertising, and distribution of opioids. These violations include:

- 25 a. Representing that prescription opioids have sponsorship, approval,
26 characteristics, ingredients, uses, benefits, or quantities that they do not have,
27

1 in violation of AS 45.50.471(b)(4);

2 b. Disparaging the goods, services, or business of another by false or
3 misleading representation of fact, in violation of AS 45.50.471(7);

4 c. Engaging in other conduct creating a likelihood of confusion or of
5 misunderstanding and which misled, deceived, or damaged a buyer or a
6 competitor in connection with the sale or advertisement of goods or services,
7 in violation of AS 45.50.471(b)(11); and

8 d. Using or employing deception, fraud, false pretense, false promise,
9 misrepresentation, or knowingly concealing, suppressing, or omitting a
10 material fact with intent that others rely upon the concealment, suppression,
11 or omission in connection with the sale or advertisement of goods or
12 services, in violation of AS 45.50.471(b)(12).

13 457. The violations include, but are not limited to, deceptively and misleadingly:

14 a. Denying that pain patients would become addicted to opioids;

15 b. Omitting that opioids are highly addictive and may result in overdose or
16 death;

17 c. Claiming that signs of addiction were “pseudo-addiction” reflecting
18 undertreated pain, and should be responded to with more opioids;

19 d. Claiming that the risk of addiction to opioids could be managed and avoided
20 through risk screening tools and other strategies;

21 e. Claiming that opioid doses can be increased, without disclosing the greater
22 risks of addiction, other injury, or death at higher doses;

- 1 f. Misleadingly comparing opioids and NSAIDs, including overstating the risks
2 of NSAIDs and citing risks of NSAIDs without disclosing risks of opioids;
3 g. Claiming that opioids are an appropriate treatment for chronic pain, and
4 failing to disclose the lack of long-term evidence for their use;
5 h. Claiming chronic opioid therapy would improve patients' function and
6 quality of life;
7 i. Claiming that "extended release" opioids provided long-lasting pain relief,
8 and failing to disclose that they do not for many patients;
9 j. Claiming abuse-deterrent opioids reduce addiction and abuse and are safer
10 than other opioids, and failing to disclose that they do not limit oral abuse,
11 can be defeated with relative ease, and may increase overall abuse; and
12 k. Promoting themselves as cooperating with law enforcement and taking any
13 available steps to prevent opioid abuse.
14

15 458. These deceptive acts and practices had the capacity and tendency to deceive
16 and were capable of being interpreted in a misleading way. In fact, these deceptive acts and
17 practices were reasonably calculated to deceive, and did in fact deceive, medical professionals
18 and the public at large for the purposes of increasing Defendants' profits for the manufacturing
19 and distributing of opioids.
20

21 459. Defendants' acts and practices were also unfair under AS 45.50.471(a).
22 These acts or practices, which relied on deceptive marketing and other misrepresentation to
23 promote addictive drugs that patients would be unable to stop taking, were immoral, unethical,
24 oppressive, or unscrupulous, caused substantial injury to consumers and businesses, and
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1 violated public policy, including, among others, the State of Alaska's efforts to curb the opioid
2 epidemic (which has become so severe that Governor Walker issued a Declaration of Disaster
3 due to a statewide "public health emergency") and the policy, reflected in 21 U.S.C. 823(e); 21
4 C.F.R. 1301.74(b) and AS 17.30.020 & 17.30.080, aimed at reducing diversion and requiring
5 reporting of suspicious orders of opioids.
6

7 460. Defendants' acts and practices also constituted unfair competition. At all
8 times relevant to this Complaint, Defendants promoted opioids as superior to other competing
9 analgesics, such as NSAIDs, and exaggerated the risks of NSAIDs while ignoring risks of
10 adverse effects of opioids.
11

12 461. As a direct result of the foregoing deceptive acts and practices, Defendants
13 obtained income, profits, and other benefits that they would not otherwise have obtained.
14

15 462. The Plaintiff has suffered actual damages, including an ascertainable loss of
16 money or property, as a result of Defendants' conduct, in violation of AS 45.50.471. The
17 Plaintiff has paid significant sums of money treating eligible patients for opioid-related
18 conditions, and has incurred other costs to address the opioid epidemic as described in this
19 Complaint.
20

21 463. Pursuant to A.S. 45.50.531 and A.S. 45.50.537, the Plaintiff is entitled to
22 actual and treble damages in amounts to be determined at trial, attorneys' fees and costs, and
23 other relief the court considers necessary and proper.
24

25 COUNT 10: STRICT PRODUCTS LIABILITY
26 DESIGN DEFECT AND FAILURE TO WARN
27 (Against Manufacturer Defendants)

464. The Plaintiff incorporates by reference all preceding paragraphs of this

1 Complaint as if fully set forth herein and further alleges as follows.

2 465. At all times material and relevant to this action, Manufacturer Defendants'
3 opioids were defective in design and failed to perform as safely as an ordinary consumer would
4 expect when used in an intended or reasonably foreseeable manner because: (1) Manufacturer
5 Defendants' opioids carried far greater risk and actual rate of addiction than the public was
6 lead to believe; (2) Manufacturer Defendants' opioids failed to provide functional
7 improvement for chronic pain patients and caused side effects, including addiction, that
8 diminished their function and quality of life; and (3) Purdue's OxyContin failed to provide the
9 12-hour relief promised, and its end-of-dose failure fueled addiction and abuse.
10

11 466. Under the circumstances, which include Manufacturer Defendants' unfair
12 and deceptive marketing and their failure to change their opioids' labels to account for post-
13 marketing information, the Manufacturer Defendants failed to provide adequate warnings that:
14 (a) clearly indicated the scope of the risk or danger posed by their opioids; (b) reasonably
15 communicated the extent or seriousness of harm that could result from this risk or danger; and
16 (c) were conveyed in a manner that would alert a reasonably prudent person.
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19 467. Manufacturer Defendants actually knew of the defective nature of their
20 opioids, but continued to market and sell them without proper warning, and with
21 misrepresentations and omissions that contradicted and undermined their drug labels, in order
22 to increase sales and profits, in conscious disregard for the foreseeable harm caused by these
23 drugs.
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468. Manufacturer Defendants knew their opioids would be used by the consumer without inspection for defect and that physicians, health care providers and patients would rely on Defendants' representations that the product was safe.

469. As a proximate cause and legal result of Manufacturer Defendants' opioids' failure to perform as reasonably expected and Manufacturer Defendants' failure to appropriately warn of known and reasonably knowable dangers associated with the use of their opioids, the Plaintiff has suffered and will continue to suffer damages as outlined in this Complaint.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff respectfully requests judgment in its favor granting the following relief:

- a) Entering Judgment in favor of the Plaintiff in a final order against each of the Defendants;
- b) An award of actual, compensatory, consequential, and incidental damages in an amount to be determined at trial;
- c) An award of all damages resulting from Defendants' violation of 18 U.S.C. § 1962(c) and (d), including prejudgment interest, the sum trebled pursuant to 18 U.S.C. § 1962(c);
- d) An Order obligating Defendants to disgorge all revenues and profits derived from their scheme;
- e) An Order ordering that Defendants compensate the Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;
- f) An Order ordering Defendants to fund an "abatement fund" for the purposes of

1 abating the public nuisance;

2 g) Injunctive relief prohibiting Defendants from continuing their wrongful
3 conduct;

4 h) An Order that the conduct alleged herein violates the Alaska UTPA and that the
5 Plaintiff is entitled to treble damages pursuant to the Alaska UTPA;

6 i) An award of the Plaintiff's costs, including reasonable attorney's fees, pursuant
7 to 18 U.S.C. § 1964(c) and/or any applicable provision of law, including the
8 Alaska UTPA;

9 j) Pre- and post-judgment interest as allowed by law; and

10 k) Any other relief deemed just, proper, and/or equitable.
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1 PLAINTIFF DEMANDS A JURY TRIAL ON ALL CLAIMS SO TRIABLE

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3 DATED: September 20, 2018
4

5
6 By: s/ Geoffrey D. Strommer

7 Geoffrey D. Strommer (AK Bar # 0911044)

8 Dawn E. Winalski (AK Bar # 1311107)

9 Edmund Clay Goodman (*pro hac vice* admission
10 pending)

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20 Attorneys for SouthEast Alaska Regional Health
21 Consortium
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